NIDA-CTN-0015 DOMAIN: SC

STUDY ENROLLMENT (ENR)

STUDY ENROLLMEN	NT (ENR)	3102112			Page 1 of 1		
NIDA-CTN-0015	Women's Treat	tment For Trauma A A Randomized		e Disorders:	Seq. Num.:		
NODE:							
CTP-SITE ID:		STUDY Visit: (circle one)	EPO(	Screening	SITNUM		
PARTICIPANT ID:	USUBJID		EPOC	OH VI	STINUW		
Assessment Date:	/	/ <u>SCDTC</u> (n	nm / dd / yyyy)	STAFF ID:			
FORM COMPLE	TION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did no	5=No	4=Not enough time to Administer 5=No Participant Contact 6=Other			

**SCORRES** 

(Research Assistant/Independent Assessor Completed)

**SCTEST** 

1.	Date informed consent was signed:	//	(mm / dd/ yyyy
	<b>_</b>		, ,,,,,,

NOTE: Boxed annotations indicate supplemental qualifier variables. Result found in QVAL field.

Modified: 7/28/2003

Printed: 9/2/2003 4:55 PM

**DOMAIN: DM and SC** 

DEMOGRAPHICS (	(DFI	M١
DEMOGRAFINGS		

PAGE 1 OF 2

NIDA-CTN-0015	Women's Tre	atm	ent For Trauma / A Randomized		e Use Disorders:	Seq. Num.:
NODE:						
CTP-SITE ID:			STUDY Visit: (circle one)	EPOC	CH Screening	VISITNUM
PARTICIPANT ID:	USUBJID					
Assessment Date:	: /	_ /	(n	nm / dd / yyyy)	STAFF ID:	
FORM COMPLE	ETION STATUS	2	=CRF Administered =Participant refused =Staff Member did no		4=Not enough time to Adn 5=No Participant Contact 6=Other	ninister

(Research Assistant/Independent Assessor Completed)

### **DEMOGRAPHICS**

1. Sex: <u>DM.SEX</u>

1 = Male
2 = Female

3. a. Ethnicity: DM.ETHNIC

1=Spanish origin, Hispanic or Latino
2=Not of Spanish origin, Hispanic or Latino (skip to question 4)

b. If Hispanic or Latino, for each of the following, please circle '1' for 'Yes' or '0' for 'No'.

<u>No</u>	Yes		
0	1	1. Mexican, Mexican-American, or Chica	no
0	1	2. Puerto Rican	QNAM=SOTHERS
0	1	3. Cuban	QLABEL=SPANISH, HISPANIC, OR LATINO: OTHER TEXT
0	1	4. Hispanic or Latino, other (specify)	IDVAR=SCSEQ

4. Race: For each of the following, please circle '1' for 'Yes' or '0' for 'No'. Circle '1' for items 'g' or 'h' if participant chooses not to answer or race is unknown. For those categories with further specification, please respond to all sub-category questions. Answer 'Yes' to <u>at least one</u> sub-category. If sub-category is unknown, select 'Other' for the sub-category and write 'Unknown' for the specify.

	No	Yes	<u>Race</u>							
	0	1	4.a. American Indian or Alaska Native							
<b>SCTEST</b>	0	1	4.b. Asian (If 'Yes', please complete 4.b.1 th	rough 4.b.7, i	if 'No', pl	lease skip to question 4.c.)				
CCOPPE			No Yes DM.RACE (If multiple,	then = M	IULTII	PLE')				
SCORRE	.5		0 1 <b>4.b.1.</b> Asian-Indian			,				
			0 1 <b>4.b.2.</b> Chinese							
			0 1 <b>4.b.3.</b> Filipino							
			0 1 <b>4.b.4.</b> Japanese	ONAM=A	OTHER	e				
			0 1 <b>4.b.5.</b> Korean	· `		OTHER TEXT				
			· · · · · · · · · · · · · · · · · · ·	IDVAR=S0		OTHER TEXT				
			- ()/_	ID V/IK=BC	СБЕО					
	0		4.c. Black or African American							
	0	1	<ol> <li>A.d. Native Hawaiian or Pacific Islander (</li> </ol>	If 'Yes', pleas	se compl	ete 4.d.1 through 4.d.4, if 'No', please				
			skip to question 4.e.)			ONAM=NOTHERS				
			No Yes			QLABEL=NATIVE HAWAIIAN OR				
			0 1 <b>4.d.1.</b> Native Hawaiian			PACIFIC ISLANDER: OTHER TEXT				
			0 1 4.d.2. Guamanian or Chamar	ro		IDVAR=SCSEQ				
			0 1 <b>4.d.3.</b> Samoan	-:e: - 1-11	_# /					
			0 1 <b>4.d.4.</b> Native Hawaiian or Pac	cific Islander,	otner (sp	Decity)				
	0	1	4.e. White	Г	ONIAM	=OOTHERS				
	0	1	4.f. Other (specify		_	CL=ETHNICITY/RACE: OTHER TEXT				
		1	<ol><li>4.g. Participant chooses not to answer</li></ol>		_	=SCSEO				
		1	4.h. Unknown	L	ID VAIC	_bcbEq				

**DOMAIN: SU** 

DEM PAGE 2 OF 2

CTP - Site ID	Participant ID	Assessment Date:		,	, Sl	וסנ	ГС	
	<u>USUBJID</u>	Assessment Date.	 m	′ - <del></del> -	 ' _y	у	у	

SUCAT=DRUG/ALCOHOL USE

5. DRUG USE: For each of the following substances, please indicate whether the substance has been used in the past 30 days. Also indicate whether the substance was ever administered by injection (IV or Non-IV). SUEVLINT=-P30D SUOCCUR=Y SUROUTE

	SUTRT SUDUR		A. PAST 30	) Days	B. EVER BY INJECTION				
	SUBSTANCE	<u>NO</u>	<u>YES</u>	NOT ASSESSED		<u>NO</u>	YES	NOT ASSESSED	
1.	Alcohol (any use at all)	0	1	9					
2.	Alcohol (to intoxication)	0	1	9					
3.	Heroin	0	1	9	[	0	1	9	
4.	Methadone/LAAM (prescribed)	0	1	9		0	1	9	
5.	Methadone/LAAM (illicit)	0	1	9	[	0	1	9	
6.	Other Opiates/Analgesics	0	1	9		0	1	9	
7.	Barbiturates	0	1	9	[	0	1	9	
8.	Other Sedatives/Hypnotics/Tranquilizers	0	1	9	[	0	1	9	
9.	Cocaine	0	1	9		0	1	9	
10.	Amphetamines	0	1	9	[	0	1	9	
11.	Cannabis	0	1	9		0	1	9	
12.	Hallucinogens	0	1	9		0	1	9	
13.	Inhalants	0	1	9		0	1	9	
14.	Nicotine (tobacco products)	0	1	9					
15.	More than 1 substance per day (including alcohol, excluding nicotine)	0	1	9		0	1	9	

### SUCAT=MAJOR DRUG PROBLEM

**SUTRT** According to the interviewer, which substance(s) is/are the major problem?

Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next to the drug in questions **01-13**. "**00**" = no problem, "**15**" = alcohol & one or more drugs, "**16**" = more than one drug but no alcohol. Ask participant when not clear.

Modified: 9/15/2003

### LIFE EVENTS CHECKLIST (LEC) =QSCAT

DOMAIN: QS PAGE 1 OF 1

### **STUDYID**

NIDA-CTN-0015	Women's Trea	tment For Trauma / A Randomized		e Use Disorders:	Seq. Num.:				
NODE:		VISITNUM							
CTP-SITE ID:		STUDY Visit: (circle one)		EPOCH Screening					
PARTICIPANT ID:	USUBJID	_							
Assessment Date:	/ QSD	<u>rc</u>	mm / dd / yyyy)		QSEVAL_				
FORM COMPLI	ETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did no	ot Administer	4=Not enough time to Ad 5=No Participant Contact 6=Other					

(Research Assistant/Independent Assessor Completed)

I am going to read a list of difficult or stressful things that sometimes happen to people. For each event I read, please tell me whether or not it <a href="https://happened.to.you">happened.to.you</a>, you <a href="https://www.witnessed.it">witnessed.it</a> or you <a href="https://www.witnessed.it">learned about it</a>.

Be sure to consider your entire life (growing up, as well as adulthood) as we go through the list of events.

### QSTESTCD/QSTEST

### **QSORRES**

	Event	a Happ to r	ened	b. Witne it	ssed	c. Learned about it		d Note	o/
		Yes	No	Yes	No	Yes	No	Yes	No
1.	Natural disaster (for example, flood, hurricane, tornado, earthquake)	1	0	1	0	1	0	1	0
2.	Fire or explosion	1	0	1	0	1	0	1	0
3.	Transportation accident (for example, car accident, boat accident, train wreck, plane crash)	1	0	1	0	1	0	1	0
4.	Serious accident at work, home, or during recreational activity	1	0	1	0	1	0	1	0
5.	Exposure to toxic substance (for example, dangerous chemicals, radiation)	1	0	1	0	1	0	1	0
6.	Physical assault (for example, being attacked, hit, slapped, kicked, beaten up)	1	0	1	0	1	0	1	0
7.	Assault with a weapon (for example, being shot, stabbed, threatened with a knife, gun, bomb)	1	0	1	0	1	0	1	0
8.	Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm)	1	0	1	0	1	0	1	0
9.	Other unwanted or uncomfortable sexual experience	1	0	1	0	1	0	1	0
10.	Combat or exposure to a war-zone (in the military or as a civilian)	1	0	1	0	1	0	1	0
11.	Captivity (for example, being kidnapped, abducted, held hostage, prisoner of war)	1	0	1	0	1	0	1	0
12.	Life-threatening illness or injury	1	0	1	0	1	0	1	0
13.	Severe human suffering If yes, specify	1	0	1	0	1	0	1	0
14.	Sudden, violent death (for example, homicide, suicide)	1	0	1	0	1	0	1	0
15.	Sudden, unexpected death of someone close to you	1	0	1	0	1	0	1	0
16.	Serious injury, harm, or death you caused to someone else	1	0	1	0	1	0	1	0
17.	Any other very stressful event or experience  If yes, specify	1	0	1	0	1	0	1	0

Modified: 7/28/2003

# SUBSTANCE USE DIAGNOSES (SUD)

# **QSCAT=SUBSTANCE USE DIAGNOSES**

DOMAIN: QS

Page 1 of 1

	4=Not enough time to Administer 5=No Participant Contact 6=Other	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer	FORM COMPLETION STATUS 2=Partic 3=Staff	FORM COMPL
D:QSEVAL	STAFF ID	——— QSDT@mm / dd / yyyy)	Date: / /	Assessment Date:
	VISITNUM EPOCH		USUBJID	PARTICIPANT ID:
	Section 2	STUDY Visit:		CTP-SITE ID:
	0			NODE:
Seq. Num.:	stance Use Disorders: Trial	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial	Women's Tr	NIDA-CTN-0015

(Research Assistant/Independent Assessor Completed)

# Diagnoses shaded gray (4,7,8,9,10) are optional. All others (1,2,3,5,6) are required.

									ည္က			
10. Other Specify:	9. Inhalants	8. Psychedelics	7. PCP	6. Cocaine	5. Opioids	4. Sedatives	3. Stimulants	2. Marijuana	QSTEST\QSTEST CSreened In	1. Alcohol		
_	1	1	1	1	1	1	1	1	CS TO	1	z	Scn
O1	51	5	5	5	Oi Oi	5	5	5	A. eenec L4A	5	~	A. Screened In J1/ J1A
z	z	z	z	z	z	z	z	z	j j	z		7 5
_	1	1	1	1	1	1	1	1	,	1	z	SC
Oi	5	5	5	5	5	5	5	5	B. Abuse L11	5	~	B. Abuse J10
z	Ν	Z	N	Ν	N	N	Ν	Z		z		ES
1	1	1	1	1	1	1	1	1		1		
2	2	2	2	2	2	2	2	2		2		- 7
ω	ω	a	s	s	ω	ω	3	3	C. Abuse Recency Code from L11	3		C. Abuse Recency Code from J10
4	4	4	4	4	4	4	4	4	C. Rec	4		C. From
o	5	9	5	5	5	5	5	5	C. Abuse Recency Code from L11	5		ecency om J10
O	0	o	o	0	o	6	6	0		0		R
z	z	z	z	z	z	z	z	z		z		S
_	_	_	1	1	-	1	1	1	Depo	1	z	Dep
Oi	On .	On .	O	9	On	01	01	5	D. Dependence Code from L22	5	~	D. Dependence Code from J21
z	z	z	z	z	z	z	z	z	nce	z		nce
_	_	_	1	1	-	1	1	1		_		
2	2	2	2	2	2	2	2	2	Dep	2		Dep
ω	ω	ω	ω	3	ω	ω	ω	3	ender Full ode	ω		ender Full Code
4	4	4	4	4	4	4	4	4	E. Dependence Recency Full Criteria Code from L22	4	QSOR	E. Dependence Recency Full Criteria Code from J22
O1	5	5	5	5	5	5	5	5	lecen ria L22	5	<u>R</u>	lecen ria J22
O	6	0	6	6	o	6	8	6	icy	8	RES	ıcy
z	z	z	z	z	z	z	Z	z		z		
	1	_	1	1	1	1	1	1		1		
2	2	2	2	2	2	2	2	2	Depe	2	_	Depe
ω	ω	ω	3	3	ω	з	ω	ω	anden Any ode t	ω	SO	anden Any ode 1
4	4	4	4	4	4	4	4	4	F. Dependence Recency Any Criteria Code from L24	4	QSORRES	F. Dependence Recency Any Criteria Code from J23
On	01	01	O1	O1	On .	9	5	01	eceni ia L24	01	S	eceni ia J23
0	8	8	8	8	0	8	8	6	, ç	8		су
z	z	z	Z	Z	z	z	z	Z		z		

# BRIEF CODING INSTRUCTIONS FOR THE CIDI CRF (To be attached to the back of the CRF)

### ALCOHOL

Column	If both J1=1 and J1A = 1 (never had 12+ drinks)	Circle "1" AND skip to Drug Section
A	If either J1=5 or J1A = 5	Circle "5" and continue with Column B
	If Interviewer Error	Circle "N" and skip to Drug Section
Column	If J10 is coded "5" (Yes) (i.e., at least one "5" coded in J6-J9)	Circle "5" Yes, continue with Column C
В	If J10 is coded "1" (No) (i.e., J6, J7 & 7A, J8, J9 are all "1")	Circle "1" No, skip to Column D
	If Interviewer Error	Circle "N" and skip to Column D
Column	If column B is coded "5"	Circle the J10 Recency code (1 - 6) in Column C
С	If column B is coded "1"	Skip Column C, and go to Column D
	If Interviewer Error	Circle "N"
Column	If J21 is coded "5"	Circle "5"
D	If J21 is coded "1" or blank due to Skip instruction on J20	Circle "1" and go to Drug Section
	If Interviewer Error	Circle "N" and go to Drug Section
Column	If Column D is coded "5"	Circle the J22 Recency code (1 - 6) in Column E
E	If Column D is coded "1"	Skip Columns E and F, and go to Drug section
	If Interviewer Error	Circle "N"
Column	If J23 is completed AND column D is coded "5"	Circle the J23 Recency code (1 - 6)
F	If J23 is not completed, OR if J23 is completed & Column D is coded "1"	Skip Column F and go to the Drug Section
	If Interviewer Error	Circle "N"

DRUG (repeat for each Drug Category assessed)

Column	If column A within the chart in question L4A = 1 for that drug category	Circle "1" AND skip to next Drug category
A	If column A within the chart in question L4A = 5 for that drug category	Circle "5" and continue with Column B
	If Interviewer Error	Circle "N" and skip to next drug category
Column B	If L11 is completed for that drug (i.e., at least one "5" coded in L8-L10)	Circle "5" Yes, continue with Column C
	If L11 not completed for that drug (i.e., L8A, L9B, L9C, L10A are all "1")	Circle "1" No, skip to Column D
	If Interviewer Error	Circle "N" and skip to Column D
Column	If column B is coded "5"	Circle the L11 Recency code (1 - 6) in Column C
С	If column B is coded "1"	Skip Column C, and go to Column D
	If Interviewer Error	Circle "N"
Column	If L22 is coded "5" for that drug category	Circle "5", continue with Column E
D	If L22 is coded "1" or blank for that drug category	Circle "1" and go to next drug category
	If Interviewer Error	Circle "N" and go to next drug category
Column	If Column D is coded "5"	Circle the L22 Recency code (1 - 6) in Column E
E	If Column D is coded "1"	Skip Columns E & F, and go to next drug category
	If Interviewer Error	Circle "N"
Column	If L24 is completed AND column D is coded "5"	Circle the L24 Recency code (1 - 6)
F	If L24 not completed, OR if L24 is completed and Column D is coded "1"	Skip Column F and go to the next drug category
	If Interviewer Error	Circle "N"

SUCAT=ALCOHOL USE **DOMAIN: SU** ALCOHOL USE (AU) PAGE 1 OF 1 Women's Treatment For Trauma And Substance Use Disorders: NIDA-CTN-0015 Seq. Num.: \_\_\_\_ A Randomized Clinical Trial NODE: Screening STUDY Visit: CTP-SITE ID: **USUBJID** (circle one) PARTICIPANT ID: Assessment Date: SUDTC/ STAFF ID: (mm / dd / yyyy) 1=CRF Administered 4-Not enough time to Administer 2-Participant refused 5-No Participant Contact FORM COMPLETION STATUS 3-Staff Member did not Administer 6=Other

(Research Assistant/Independent Assessor Completed)

	SUTRT	SUEVLINT=-P6M	SUOCCUR
1.	'//	any alcoholic beverage (beer, wine, or liquor) since  ' (6 months prior to today's date)?  'e as mm/dd/yyyy)	(0=No, 1=Yes)
		SUDUR	

**SUROUTE** 

CTN-0015 Alcohol Use.doc Modified: 10/26/2004 Printed: 1/29/2009 3:06 PM

### PRISM SUICIDAL AND HOMICIDAL INTENT (PRSM)

DAGE 1 OF 2

NIDA-CTN-0015   Women's Treatment For Trauma And Substance Use Disorders:   Seq. Num.:	T TELEVILLE	AND HOMICIDAL	111 E 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	,		1.0	GE TUF Z			
STUDY Visit: (circle one)	NIDA-CTN-0015	Women's Treatme			Use Disorders:	Seq. Num	.:			
FORM COMPLETION STATUS   2-Participant refused   3-Staff Member of and Administer   5-Other	CTP-SITE ID: PARTICIPANT ID:	USUBJID QSDTC /	(circle one)	nm/dd/yyyy)	STAFF ID:	ID:				
1. Recurrent thoughts of death:		3	-Staff Member did no		5-No Participant Cor	ntact				
Did you ever think you would be better off dead?      Did you feel as though you wanted to die (did you wish you wouldn't wake up in the morning when you went to bed at night?)      IF UNCLEAR: Can you describe these thoughts/feelings? How often were you thinking about these things?      IF YES: Do you still have these thoughts/feelings at the present time? How often? For how long have you been having these thoughts/feelings?      IF YES: Do you still think about killing yourself? (What did you think of? How often did you have that thought?)      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?      IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?	SUICIDALIT	·	1		1.0					
<ul> <li>Did you ever think about suicide or killing yourself? (What did you think of? How often did you have that thought?)</li> <li>IF YES: Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?</li> <li>Must have a thought about this at least three times in a week.</li> <li>Must think actively of killing oneself, even if ambivalent.</li> <li>Can have suicidal ideation without having suicidal plan.</li> <li>Emprior to the past 6 months</li> <li>Specific suicide plan</li> </ul>	about death or of you would be be  Did you feel as the die (did you wish up in the mornin bed at night?)  IF UNCLEAR: Of these thoughts/feelings were you thinking.  IF YES: Do you thoughts/feelings How often? For been having the	lying? Do you think etter off dead? hough you wanted to n you wouldn't wake g when you went to can you describe eelings? How often ng about these things? still have these s at the present time? how long have you se thoughts/feelings?	about dea week (not  Include re would be lealth pro occur with status.  Exclude p when som long as prilevel.	th at least three necessarily all current thought better off dead. oughts of death oblem or HIV strout a change in reoccupation wheene close is ill eoccupation is	times in a day).  Is that she  In attributed to atus that in health  If the death is at expected in a stributed to attributed to attribute t	Absent)  (Sub-threshold)  3  =Prior to the past =In the past 6 mo	3 (Present) 6 months			
having these thoughts?  2=In the past 6 months  3. Specific suicide plan	Did you ever thir killing yourself? of? How often di thought?)     IF YES: Do you yourself at the pi	nk about suicide or (What did you think id you have that still think about killing resent time? How	Must think     even if an     Can have	e times in a wee actively of killi nbivalent. suicidal ideatio	ng oneself,  B  n without	1 2 (Sub-threshold) 3	3 (Present)			
A. Rating Scale:						·				

- Did you ever think of any specific plan for committing suicide? What did you think of doing?
- IF YES: When was that? For how long did you think of this plan? How often would you think about this plan?
- . IF YES: Do you think of any specific plan for committing suicide at the present time? What do you think of doing? How often do you think about it? For how long have you been thinking about this plan?
- Must be thinking of actual method of suicide.
- . Intent to carry out the plan is not required; formulation of a specific plan is enough.
- · Include even if fleeting plan.

Modified: 10/24/2003

Need not have been recurrent or feasible.

1 (Absent)	2 (Sub- threshold)	3 (Present)

1=Prior to the past 6 months

2=In the past 6 months

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PRSM DOMAIN: QS PAGE 2 OF 2

### 4. Suicide gesture

- Did you start to do something in order to kill yourself, even if you changed your mind and stopped, or if someone else stopped you? What did you do? What happened then? What were you thinking of when you did that?
- IF YES: When was that? How many times did this happen?

### OSTESTCD/OSTEST

- Must be thinking about suicide at time of act but believe that the extent of action taken would not actually result in death
- Include apparent suicide gesture even if subject claims intent was only attention-seeking
- Exclude self-mutilation for tensionrelief
- · Exclude preparation for attempt

### A. Rating Scale:

1 2 3 (Present) threshold)

В. \_\_\_\_

1=Prior to the past 6 months

2=In the past 6 months

QSORRES QSEVLINT

### 5. Suicide attempt

- Did you ever do anything to hurt or kill yourself? Did you do anything on purpose that you knew could have killed you? (What did you do? What happened then? Did you think you could die as a result?)
- IF YES: When was that? How many times did you do anything to kill yourself?
- Need not to have been planned or premeditated; include totally impulsive attempts
- Very impulsive suicide behavior can occur even when other death/suicide items are negative
- Include if completed act was believed to be lethal but subject was discovered and saved
- Must have believed that act was lethal, regardless of objective lethality

### A. Rating Scale:

1 3 (Absent) (Present)

В. \_\_\_\_

1=Prior to the past 6 months

2=In the past 6 months

### HOMICIDALITY

### 6. Recurrent homicidal ideation:

- Did you ever think about harming or killing someone? (What did you think of? How often did you have that thought?)
- IF YES: Do you still think about harming or killing someone at the present time? How often? For how long have you been having these thoughts?
- Must think actively of harming or killing someone, even if ambivalent.
- Can have homicidal ideation without having homicidal plan.

### A. Rating Scale:

1 2 3 (Present) threshold)

В. \_\_\_

1=Prior to the past 6 months

2=In the past 6 months

### (If Homicidal Ideation in past 6 months, above, ask question 7.)

### 7. Specific homicide plan

- Have you taken any steps toward carrying out this plan?
- IF YES: What have you done?
- Must be thinking of actual method of harming or killing someone.
- Intent to carry out the plan is not required; formulation of a specific plan is enough.
- Include even if fleeting plan.

Modified: 10/6/2003

 Need <u>not</u> have been recurrent or feasible.

### A. Rating Scale:

1 (Absent)

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(Present)

# MINI MENTAL STATUS EXAM (MMSE) = OSCAT STUDYID DOMAIN: QS PAGE 1 OF 4

		- <del></del>			17102 101 1		
NIDA-CTN-0015	Women's Trea		ent For Trauma And Substance Use Disorders: A Randomized Clinical Trial				
NODE:				EPOCH \	VICITALLIM		
CTP-SITE ID:		STUDY Visit: (circle one)		Screening	VISITNUM		
PARTICIPANT ID:	USUBJII	0					
Assessment Date	: /	_ / _ QSDTC(n	nm / dd / yyyy)	STAFF ID:	QSEVAL		
FORM COMPLI	ETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other			

(Research Assistant/Independent Assessor Completed)

### For each question, check the correct responses, then enter the total score at left

1. What is the: QSORRES		Maximum Score: [5]
Year?		1-1
Season? Date?		
Date? Day?		
Month?		
2. Where are we:		[5]
State? County?		
County? Town?		
Street?		
Number? 3. Name 3 objects:		191
5. Name 5 objects. Orange		[3]
Airplane		
Tobacco	OR:spell WORLD backwards:	161
4. Count backwards by 7's, starting at 100: 93	OR.spell WORLD backwards.	[5]
86	(L)	
	(R) (O)	
	(w)	
5. Recall 3 objects:		[3]
Orange		
Airplane		
Tobacco		101
6. Name a: Pencil		[2]
Watch		
7. Repeat the following:		[1]
"No ifs, ands, or buts."		
<del>-</del> · · ·		ro1
8. Follow a 3 stage command:	band	[3]
A. Take a paper in your right I B. Fold it in half.	nand.	
C. Put it on the floor.		
For the following three items hand pages 2-4 to the partic	cipant, and ask her to follow the directions. Reco	rd the results below.
9. Reading and obeying provided item		[1]
10. Copying provided design		[1]
11. Writing sample		[1]
HAND MMSE Score (sum scores fi	rom questions 1 thru 11)	[30]
IIAND MINISE SCORE (SUM SCORES II	ioni questions i una i i)	[Ju]

CTN-0015\_MMSE\_v1-1.doc Modified: 9/5/2003 Printed:9/11/2003 5:05 PM

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### PARTICIPANT SECTION Hand to participant to complete this section.

QSTESTCD/QSTEST

QSORRES

(9) Read and obey:

# "Close Your Eyes"

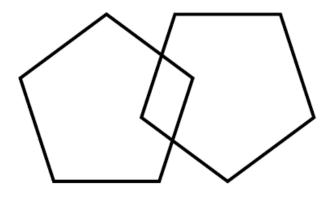
MMSE =QSCAT PAGE 3 OF 4

CTP - Site ID	Participant ID	Assessment Date:QSDTC	ТС	/				7			
			m	m	d	·	у_	_у	у	у	

# PARTICIPANT SECTION Hand to participant to complete this section.

(10) Copy the design of the intersecting pentagons (BELOW).

QSTESTCD/QSTEST QSORRES



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MMSE =QSCAT

PAGE 4 OF 4

MINISE		FAGE 4 OF 4							
CTP - Site ID	Participant ID <u>USUBJID</u>	Assessment Date: / QSDTC/							
PARTICIPANT SECTION Hand to participant to complete this section.									
(11) Write a sentence:	QSTESTCD/QSTE	ST							
( · · / · · · · · · · · · · · · · · · ·	QSORRES								

STUDYID DOMAIN: CM

### PRIOR AND CONCOMITANT MEDICATIONS (PCM)

PAGE 1 OF 2

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NIDA-CTN-0015	Women's Trea	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial				
NODE:			E		TNUM seline	
CTP-SITE ID:		STUDY Visit: (circle one)	1-W	6-Month FUP		
PARTICIPANT ID:	USUBJII	0		12-Month FU	IP	
Assessment Date: / CMD		O (mm / dd / yyyy)		y) STAFF ID:		
FORM COMPLE	TION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact er 6=Other		

(Research Assistant/Independent Assessor Completed)

Complete one CRF for each <u>prescription</u> medication the participant is taking for emotional, psychological, or psychiatric purposes. If a previously recorded medication's dose has changed, complete a new CRF for the medication and the new dosage.

Since your last visit\*...

- Have there been any dosage changes for prescription medications you are currently taking for emotional, psychological, or psychiatric purposes?
- Have you discontinued any of the prescription medications for emotional, psychological, or psychiatric purposes?
- Have you started any new prescription medications for emotional, psychological, or psychiatric purposes?

\*For the Screening visit assess the past 30 days. For the 1-Week Follow-Up, assess all prescription medications taken during Treatment Phase (study weeks 1 thru 6). For all other visits, assess period since last visit.

	1.	New med or changed med 0=No (End questionnaire) 1=Yes (Continue with questions 2 thru 11)  Note: data only converted if PCM001 = 1				
CMSPID	2.	Medication number	Medication number			
QNAM=CMPRENU M QLABEL= MEDICATION NUMBER OF PREVIOUSLY CMIND	4. 5.	Report type 1=New medication (not previously recorded) 2=Change in dose of a previously recorded in the description of the desc	viously e; other	recorded medication		
RECORDED	б.	Purpose/Indication (Reason drug is being taken): 1=Anti-depressants				
MEDICATION IDVAR=CMSEQ		2=Anti-anxiety QNAM=CMREPTYP		ABEL=MEDICATION REPORT TYPE		
CMDOSE		6=Other (specify:		)		
CMDOSU	7. 8. 9.	Dosage quantity (i.e., 1200)  Dosage units (Use units codes on the next percent status of medication	page)	QNAM=CMMDSTAT QLABEL=MEDICATION STATUS IDVAR=CMSEQ		
10.		1=Continuing (Participant still taking med) 2=Discontinued (Participant no longer takin	1=Continuing (Participant still taking med) 2=Discontinued (Participant no longer taking med – complete question 11)			
		Start date (Date started or dose changed)	/	CMS/TDTC (mm/dd/yyyy)		
	11.	Stop date (Date discontinued or changed)	/	CMENDTC (mm/dd/yyyy)		

Modified: 10/28/2003

PCM

CTP - Site ID	Participant ID	Assessment Date:			/		/	_		_
			m	m	d	d	У	У	У	у

Dosage units										
1 = grain(s) 6 = microgram(s) / kilogram 11 = milligram(s)										
2 = gram(s)	7 - microgram(s) / sq. meter	12 = milligram(s) / kilogram								
3 - International units	8 - microlitre(s)	13 - milligram(s) / sq. meter								
4 = microcurie(s)	9 - milicurie(s)	14 - millitre(s)								
5 - mlcrogram(s)	10 - milliequivalent(s)	88 - Other								
		99= Unknown								

PAGE 2 OF 2

NOTE: Boxed annotations indicate supplemental qualifier variables. Result found in QVAL field. DOMAIN: QS **STUDYID** CAPS DIAGNOSIS SUMMARY (CAPS) = QSCAT PAGE 1 OF 2 Women's Treatment For Trauma And Substance Use Disorders: NIDA-CTN-0015 Seq. Num.: A Randomized Clinical Trial NODE: Screening **EPOCH** VISITNUM STUDY Visit: CTP-SITE ID: 1-Wk FUP 3-Month FUP (circle one) **USUBJID** 12-Month FUP 6-Month FUP PARTICIPANT ID: QSDTC / **QSEVAL** STAFF ID: Assessment Date: \_ (mm / dd / yyyy) 1=CRF Administered 4-Not enough time to Administer FORM COMPLETION STATUS 2-Participant refused 5=No Participant Contact 3-Staff Member did not Administer (Independent Assessor Completed) QNAM=QSINT, IDVAR=QSSEQ A. TRAUMATIC EVENT(s) OLABEL=SYMPTOM INTENSITY (1) Traumatic event(s) or worst traumatic event(s) (Describe briefly. Record up to 3 events, 200 chars. max): QNAM=QSFREQ, IDVAR=QSSEQ QSORRE QLABEL=SYMPTOM FREQUENC' B. REEXPERIENCING SYMPTOMS Frequency Present\* Intensity (a) (b) (c) QSTESTCD/QSTEST Nο Yes Intrusive recollections 3 Distressing dreams 0 1 3 4 0 1 2 3 4 1 (3) Acting or feeling as if event were recurring 1 3 2 3 4 0 1 (4) Psychological distress at exposure to cues 0 1 3 4 0 2 3 4 0 1 0 3 4 2 3 1 (5) Physiological reactivity on exposure to cues -1 0 1 0 \*(Symptom present if Frequency ≥ 1 and Intensity ≥ 2) (6) Number of Criterion B symptoms (need 1): QNAM=QSCRITB, IDVAR=QSGRPID, QLABEL= NUMBER OF CRITERION B SYMPTOMS

C. AVOIDANCE AND NUMBING SYMPTOMS				(a)	ency	'		int	ensi (b)	ty		Pres (d No	sent* c) Yes
(1)	Avoidance of thoughts, feelings, or conversations	0	1	7	3	4	0	1	2	3	4	0	1
(2)	Avoidance of activities, places, or people	0	1	2	3	4	0	1	2	3	4	0	1
(3)	Inability to recall important aspect of trauma	0	1	1	3	4	0	1	2	3	4	0	1
(4)	Diminished interest or participation in activities	0	1	2	3	4	0	1	2	3	4	0	1
(5)	Detachment or estrangement	0	1	1	3	4	0	1	2	3	4	0	1
(6)	Restricted range of affect	0	1	1	3	4	0	1	2	3	4	0	1
(7)	Sense of a foreshortened future	0	1	1	3	4	0	1	2	3	4	0	1

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(8) Number of Criterion C symptoms (need 3)

QNAM=QSCRITC, IDVAR=QSGRPID, QLABEL= NUMBER OF CRITERION C SYMPTOMS

CTN-0015\_CAPS\_Diagnosis\_Summary\_v1-1.doc

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<sup>\*(</sup>Symptom present if Frequency > 1 and Intensity > 2)

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QNAM=QSINT, IDVAR=QSSEQ QLABEL=SYMPTOM INTENSITY 2 CAPS DIAGNOSIS SUMMARY (CAPS) = QSCAT CTP - Site ID Participant ID Assessment Date: **USUBJID** m QNAM=QSFREQ, IDVAR=QSSEQ **QSORRES** QLABEL=SYMPTOM FREQUENCY Frequency D. HYPERAROUSAL SYMPTOMS Present\* Intensity (a) (b) QSTESTCD/QSTEST (c) No Yes Difficulty falling or staying asleep 0 3 4 (1) Irritability or outbursts of anger 0 2 3 4 1 3 2 3 4 (3) Difficulty concentrating 4 0 1 3 n 0 1 (4) Hypervigilance 0 2 3 4 0 1 3 4 0 1 (5) Exaggerated startle response 0 2 3 4 0 1 4 1 \*(Symptom present if Frequency ≥ 1 and Intensity ≥ 2) QNAM=QSCRITD (6) Number of Criterion D symptoms (need 2) IDVAR=QSGRPID, OSORRES QSTESTCD/QSTEST QLABEL= NUMBER OF E. DURATION OF DISTURBANCE NO CRITERION D SYMPTOM\$ YES Duration of disturbance at least one month 0 (1)At what age did you first start having these symptoms you've told me about? (2)**QSORRES** OSTESTCD/OSTEST F. SIGNIFICANT DISTRESS OR IMPAIRMENT IN FUNCTIONING Intensity 0 2 4 Subjective distress 3 Impairment in social functioning 4 (2)1 3 4 Impairment in occupational functioning - 1 2 3 (3)NO YES 1 (4) AT LEAST ONE ≥ 2? QSTESTCD/QSTEST **QSORRES** G. PTSD DIAGNOSIS Diagnosis (select one)

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- 1 = Full PTSD All Criteria (A-F) are met
- 2 = Subthreshold PTSD Criteria A, B, E, F, plus either C or D are met
- 3 = No Full or Subthreshold PTSD

**STUDYID** 

**DOMAIN: IE** 

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### INCLUSION - EXCLUSION CHECKLIST (IEC)

_	-	

INCLUSION EXCLU	OION OTILONEIST	\.= = /			TAGETOTT
NIDA-CTN-0015	Women's Treatmen	Seq. Num.:			
NODE:			E	EPOCH	
CTP-SITE ID:		STUDY Visit: (circle one)	_	Screening /ISITNUM	ı
PARTICIPANT ID:	USUBJID				
Assessment Date:	/ <u>  IEDT</u> C/ _	(mm	dd / yyyy)	STAFF ID:	
FORM COMPL	LETION STATUS	1=CRF Administers 2=Participant refus 3=Staff Member do	ed	5=No Participan	me to Administer It Contact

(Research Assistant/Independent Assessor Completed)

1.	NCLUSI	ON CF	RITER	RIA IECAT
YES	NO	UNK		. IETEST
1	0	-9	1a.	Participant is female, and between 18 and 65 years old.
1	IEORRE	S _9	1b.	Participant has used an illicit substance within the past six months and has current diagnosis of illicit drug abuse or dependence (with or without alcohol) or has used alcohol within the past 6 months and has current diagnosis of alcohol abuse or dependence.
1	0	-9	1c.	Participant is diagnosed as having either: a. Full PTSD (meets criteria A, B, C, D, E, F). b. Subthreshold PTSD (meets criteria A, B, E, F, plus either C or D).
1	0	-9	1d.	Participant has given informed consent.
1	0	-9	1e.	Participant is enrolled in treatment at the CTP.

If any of the inclusion questions above have been answered NO or UNKNOWN then the participant is not eligible and cannot be entered or randomized into the study. Please continue to question 2a.

2. E	XCLU	SION C	RITE	RIA
YES	NO	UNK		
1	0	-9	2a.	Participant has an advanced stage medical disease (i.e. AIDS, TB) as indicated by global physical deterioration and incapacitation.
1	0	-9	2b.	Participant has an impaired mental status (MMSE score is less than 22).
1	0	-9	2c.	Participant has significant risk of suicidal intent, behavior or history.
1	0	-9	2d.	Participant has current homicidal intent or plan.
1	0	-9	2e.	Participant has history of a schizophrenio-spectrum diagnosis.
1	0	-9	2f.	Participant has a history of active (past two months) psychosis.
1	0	-9	2g.	Participant is involved in litigation concerning PTSD.
1	0	-9	2h.	Participant refuses to be audio-taped or video-taped.

If any of the Exclusion questions above are answered YES or UNKNOWN, the participant is not eligible and cannot be entered or randomized into the study. Please continue to question 3a.

YES	NO	UNK		SC.SCORRES				
1	0	-9	3a.	the participant eligible for the study? If no or unknown, skip to 3c.				
	SC.SCTE	EST	3b.	Date of eligibility:/ (mm / dd / yyyy)				
			3c.	Specify ineligibility:				

Modified: 9/29/2004

ADDICTION SEVER				DOMA	AIN: QS PAGE 1 OF 14			
NIDA-CTN-0015	Women's Treatme	ent For Trauma A A Randomized (		e Use Disorders:	Seq. Num.:			
NODE: CTP-SITE ID:		STUDY Visit: (circle one)		OCH Baseline	'			
PARTICIPANT ID:	<u>USUBJID</u>		VIOI	THOM				
Assessment Date:	//	QSDTC (m	m / dd / yyyy)	STAFF ID: _	QSEVAL			
FORM COMPLE	TION STATUS 2	-CRF Administered -Participant refused -Staff Member did not	Administer	4-Not enough time to Ar 5-No Participant Contact 6-Other	dminister st			
(Independent Assesso	or Completed)							
Participant Date of I	Birth (mm/dd/yyyy):	// Composite (for site us						
	Medical:	Leg	jal: _					
	Employment:	Far	nily: _					
	Drug:	Psy	chiatric: _					
	Alcohol:							
				_				
Patient Rating Scale  0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely	Family/Social, a gathered is cont There are two ti 1. The 2. Life  Patient Rating me know how b important treatn  Please refer to the	ind Psychological. In fidential. In periods we will on a past 30 days time Data Scale: Patient inpurate of the Patient Rating Someon the the Patient Rating Someon and infortable giving and	edical, Employm All clients received discuss: It is important, een by any prote e area being discale in the adja answer, then do	For each area, I will as plems in each section. scussed. cent key.	interview. All information  sk you to use this scale to let I will also ask you how			
41		Interviewer Ir	structions					
1. Leave no blanks. 2. Make plenty of Comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems). 3. Throughout the ASI, when noted: X = Question not answered. N = Question not applicable. 4. Terminate interview if client misrepresents two or more sections. 5. When noting comments, please write the question number.  HALF TIME RULE: If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.								

CONFIDENCE RATINGS: ⇒ Last two items in each section.

⇒ Do not over interpret.

⇒ Denial does not warrant misrepresentation.

⇒ Misrepresentation = overt contradiction in information. Probe and make plenty of comments! ASL PAGE 2 OF 14

CTP - Site ID	Participant ID	Assessment Date:		/		_	/	_		_
			m	m	d	d	у	у	у	у

### Hollingshead Categories

- 1 = Higher Executive, Major Professionals, Owner of Large Business
- 2 = Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)
- 3 = Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
- 4 = Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
- 5 = Skilled Manual—usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
- 6 = Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
- 7 = Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include Unemployed.
- 8 = Homemaker
- 9 = Student/No Occupation/Disabled

### List of Commonly Used Drugs

Alcohol: Beer, wine, liquor Methadone: Dolophine, LAAM

Opiates: Pain killers = Morphine, Diluaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4,

Syrups = Robitussin, Fentanyl

Barbiturates: Nembutal, Seconal, Tuinol, Ámytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol

Sed/Hyp/Tranq: Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown,

Other = ChloralHydrate (Noctex), Quaaludes

Cocaine: Cocaine Crystal, Free-Base Cocaine or "Crack, and "Rock Cocaine"

Amphetamines: Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal

Cannabis: Marijuana, Hashish

Hallucinogens: LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy

Inhalants: Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants,

Ulcer Meds = Zantac, Tagamet

Asthma Meds = Ventoline Inhaler, Theodur Other Meds = Antipsychotics, Lithium

### Alcohol/Drug Section Instructions

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol /drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

- 30 day questions only require the number of days used.
- ⇒ Lifetime use is asked to determine extended periods of use.
- ⇒ Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
- Alcohol to intoxication does not necessarily mean "drunk", use the words "felt the effects", "got a buzz", "high", etc. instead of intoxication. As a rule of thumb, 5+ drinks in one setting, or within a brief period of time defines "intoxication".
- ⇒ How to ask these questions:
  - → "How many days in the past 30 have you used....?
  - → "How many years in your life have you regularly used....?"

ASL DOMAIN: QS PAGE 3 OF 14

CTP - Site ID	Participant ID	Assessment Date: / QSDTC	
	UŞUBJID	m m d d y y y y	

### GENERAL INFORMATION =QSSCAT

QSORRES		QSTEST	
——————————————————————————————————————	G9.	Contact code: 1=In person	Comments:
		2=Telephone (Intake ASI must be in person)	
		3=Mall X=Not Answered	
	G12.	Special:	
		3-Patient refused 3-Patient unable to respond	
		N=Not Applicable	
QSORRESU:		R / QSORRESU=MONTH How long have you lived at your current address?	
a. Yrs. b. Mos		(XXXXX=Not Answered)	
-			Data not entered
	G18.	Do you have a religious preference? 1-Protestant 5-Other (specify )	Data not entered
		2=Catholic 6=None 3=Jewish X=Not Answered	
		4-Islamic	
	G19.	QSEVLINT=-P30D Have you been in a controlled environment in the past 30	
		days? A place, theoretically, without access to drugs/alcohol.	
		2=Jall 6=Other (specify)	
		3=Alcohol or Drug Treatment X=Not Answered 4=Medical Treatment	
	G20.	How many days? "NN" if question G19 is "No". Refers to total number of days detained in the past 30 days. (XX=Not Answered)	
		QSEVLINT=-P30D QSORRESU=DAY	

ASL DOMAIN: QS PAGE 4 OF 14

CTP - Site ID	Participant ID	Assessment Date: /	/	QSDTC
		m m	d d	у у у у

## MEDICAL STATUS =QSSCAT

### **QSTEST**

QSORRES	M1.	How many times in your life have you been hospitalized for medical problems?	Comments:
		Include O.D.'s, D.T.'s. Exclude detox, alcohol/drug, and psychiatric treatment and childbirth (if no complications). Enter the number of overnight hospitalizations for medical problems. (XX=Not Answered)	
 0=No. 1=Yes	М3.	Do you have any chronic medical problems which continue to interfere with your life?	
u-140, 1-160		A chronic medical condition is a serious physical or medical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities. (X=Not Answered)	
		If "Yes," specify:	
 0=No. 1=Yes	M4.	Are you taking any prescribed medication on a regular basis for a physical problem?	
- 1		Medication prescribed by a MD for medical conditions; not psychiatric medicines. Include medicines prescribed whether or not the patient is currently taking them. The Intent is to verify chronic medical problems. (X= Not Answered)	Data not entered
		If "Yes," specify:	
 0=No, 1=Yes	M5.	Do you receive a pension for a physical disability? (X= Not Answered)	
,		Include Workers' compensation, exclude psychiatric disability.	
		If "Yes," specify:	
——	M6.	Howngan days have you experienced in the past 30 days?	
		Do not include aliments directly caused by drugs/alcohol. Include flu, colds, etc. Include serious aliments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.). (X=Not Answered)	
		Questions M7 & M8, please ask the patient to use the ent Rating scale.	
	M7.	How troubled or bothered have you been by these medical problems in the past 30 days?	
		Restrict response to problem days of Question M6. (X=Not Answered)	
	M8.	How important to you <u>now</u> is treatment for these medical problems?	
		Refers to the need for new or additional medical treatment by the patient. $(X=Not\ Answered)$	
	CON	FIDENCE RATINGS	
	Is the	e above information significantly distorted by:	
0=No, 1=Yes	M10.	Patient's misrepresentation?	
0=No, 1=Yes	M11.	Patient's inability to understand?	

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ASL DOMAIN: QS
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AUL		TAGESON	
CTP - Site ID	Participant ID	Assessment Date: / QSDTC	$\neg$
	USUBJID	m m d d y y y y	

EMPLOYME	NT/SUPPORT STATUS =QSSCAT	
	AR / QSORRESU=MONTH E1. Education completed? QSTEST  GED = 12 years. Include formal education only. (XXXX=Not Answered)	Comments:
QSOR <u>RESU=</u> MON Mos. QSORRES	Training or technical education completed:  Formal/organized training only. For military training, only include training that can be used in civilian life (i.e., electronics or computers). (XX=Not Answered)	
0=No, 1=Yes	E4. Do you have a valid driver's license? Valid license; not suspended/revoked. (X=Not Answered)	
0=No, 1=Yes	E5. Do you have an automobile available? ( <u>If answer to E4 is "No"</u> , then E5 must be "No") Does not require ownership, only requires availability on a regular basis.	
QSORRESU=YE/	(X=Not Answered)  AR / QSORRESU=MONTH  E8. How long was your longest full time job?  Full time = 35+ hours weekly; does not necessarily mean most recent job.	
	(XX/XX=Not Answered)  E7. Usual (or last) occupation? (specify):  (use Hollingshead Categories Reference Sheet) (X=Not Answered)	
0=No, 1=Yes	E9. Does someone contribute the majority of your support?  Is patient receiving any regular support (i.e., cash, food, housing) from family/friend? Include spouse's contribution; exclude support by an institution. (X=Not Answered, N=Not Applicable)	Data not entered
	QSEVLINT=-P3Y E10. Usual employment pattern, past three years?  1 = Full time (35+ hrs/wk) 6 = Retired/Disability 2 = Part time (regular hours) 7 = Unemployed 3 = Part time (irreg., day work) 8 = in controlled environment 4 = Student (X=Not Answered) 5 = Military Service Answer should represent the majority of the last 3 years, not just the most	
QSORRESU QSEVLINT=-I	=DAY recent selection. If there are equal times for more than one category, select that which best represents the more current situation.	
Max=\$99999	For questions E12-E17: How much money did you receive from the following sources in the past 30 days?	
\$	E12. Employment (net income)? (Net or "take home" pay, Include any "under the table" money.) (XXXXX=Not Answered)	
\$	E13. Unemployment Compensation? (XXXXX=Not Answered)	QSEVLINT=-P30D QSORRESU=DOLLAR
\$	E14. Welfare? (Include food stamps, transportation money provided by an agency to go to and from treatment.) (XXXXX=Not Answered)	
\$	E15. Pensions, benefits or Social Security? (Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.) (XXXXX=Not Answered)	

ASL DOMAIN: QS
PAGE 6 OF 14

					I NOL O OI 14
CTP - Site ID		Participant ID <u>USUBJID</u>	Assessment Date:	//	QSDTC y y y
S_QSORRES E	clo	OSTEST ate, family or friends? (Money for p thing), include unreliable sources of inco sh payments only, include windfalls (unex mbling, inheritance, tax returns, etc.). (XX	me (e.g., gambling). Record pected), money from loans,	Comments:	
\$ E	Ca ga	egal? (XXXXX=Not Answered) sh obtained from drug dealing, stealing, inbling, prostitution, etc. Do Nor attempt a dollar value.			
Max = 99	fo: Mu do	ow many people depend on you f od, shelter, etc.? ust be regularly depending on patient, do not include the patient or self-supporting iswered)	include alimony/child support,		
E	pro Inc pro	ow many days have you experient oblems in the past 30 days? Single Inability to find work, if they are activablems with present job in which that job isswered)	QSEVLINT=-P30D QS0 vely looking for work, or	DRRESU=DAY	
<u>R</u>	Rating so The patient	stions E20 & E21, ask the patie cale. QSEVLINT=-P3 's ratings in Questions E20 & E21 refer to reparing for a job, not giving them a job.	0D	Data not ente	red
E	en If t	ow troubled or bothered have you nployment problems in the past 3 he patient has been incarcerated or detal by cannot have employment problems. (2)	0 days? ned during the past 30 days,		
E		ow important to you <u>now</u> , is couns nployment problems? (X=Not Answ			
С	ONFIDE	ENCE RATINGS			
ls	s the abo	ove information <u>significantly</u> disto	rted by:		
0=No, 1=Yes	23. Pa	atient's misrepresentation?			
0=No, 1=Yes	24. Pa	atient's inability to understand?			

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CTP - Site ID	Participant ID	Assessment Date:	,		,	QS	DT	С	$\neg$
	USUBJID	Assessment Date.	 m ′	d	 ′	у	- <u>y</u>		

# DRUG/ALCOHOL USE =QSSCAT

Route of Administration Types:

1 = Oral 2 = Nasal 3 = Smoking 4 = Non-IV injection 5 = IV injection

Note the <u>usual or most recent</u> route. For more than one route, choose the most severe. The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be coded as "N." (XX=Not Answered)

QSEVLINT=-P30D

	QSEVLINT=-F30D								
Sub	stance QSTEST	a. Past 30 Days	b. Lifetime Use (Years)	c. Route of Admin.	Comments:				
D1.	Alcohol (any use at all)		QSORRES						
D2.	Alcohol (to intoxication)								
D3.	Heroin								
D4.	Methadone/LAAM (prescribed)								
D4a.	Methadone/LAAM (illicit)								
D5.	Other Opiates/Analgesics								
D6.	Barbiturates								
D7.	Other Sedatives/Hypnotics/Tranquilizers								
D8.	Cocaine								
D9.	Amphetamines								
D10.	Cannabis								
D11.	Hallucinogens								
D12.	Inhalants								
D36.	Nicotine (tobacco products)								
D13.	More than 1 substance per day (including alcohol, excluding nicotine)								

		,				
<ol> <li>More than 1 s</li> <li>(including alo</li> </ol>		per day iding nicotine)				
— — D14. According major pro interviewer (excluding N 01-12 (code problem,		major problem interviewer shouk (excluding Nicotin 01-12 (code preso problem, "15" drug, but no alcoh	he interviewer, 19 19 d determine the ma e use). Code the n cribed or illicit meth " = alcohol & one o	which substance gor drug or drugs of a number next to the dr adone as "04"). "00 or more drugs, "16" = t when not clear. (XX	abuse ug in questions o" = no more than one	Comments:  Data not entered
	How m	nany times hav	e you:			
	D17.	after last drink, or by shaking, sever	significant decreas	emens (DT's): Occur se in alcohol intake. ( ver, hallucinations, th inswered)	Characterized	

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	OSTEST	
OCODDEC	How many times in your life have you been treated for: Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if 3+ meetings within one month period). (XX=Not Answered)	Comments:
QSORRES	D19. Alcohol abuse?	
	D20. Drug abuse?	
	How many of these were detox only?	
	D21. Alcohol? If D19 = "00", then question D21 is "NN" (XX=Not Answered)	
	D22. Drugs? If D20 = "00", then question D22 is "NN" (XX=Not Answered)	
Max =\$99999	How much money would you say you spent during the past 30 days on: Only count actual money spent. What is the financial burden caused by drugs/alcohol? (XXXXX=Not Answered)	Data not entered
\$	D23. Alcohol? QSORRESU=DOLLAR	
\$	D24. OSEVLINT=-P30D QSORRESU=DOLLAR	
	D25. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include AA/NA) (XX=Not Answered) QSEVLINT=-P30D QSORRESU=DAY	
	For questions D28 - D31, please ask the patient to use the Patient Rating scale.  The Patient is rating the need for additional substance abuse treatment. (X=Not Answered)	
	How many days in the past 30 have you experienced:	
	D26. Alcohol problems? QSEVLINT=-P30D QSORRESU=D	AY
	How troubled or bothered have you been in the past 30 days by these:	
	D28. Alcohol problems? QSEVLINT=-P30D QSORRESU=	DAY
	How important to you now is treatment for these:	
	D30. Alcohol problems?	
	How many days in the past 30 have you experienced:	
——	D27. Drug problems? Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to. (XX=Not Answered)	
	How troubled or bothered have you been in the past 30 days	
	by these: QSEVLINT=-P30D D29. Drug problems? QSEVLINT=-P30D	
	How important to you now is treatment for these:	
	D31. Drug problems?	
	CONFIDENCE RATINGS	
	Is the above information significantly distorted by:	
0=No, 1=Yes	D34. Patient's misrepresentation?	
0=No, 1=Yes	D35. Patient's inability to understand?	

ASL PAGE 9 OF 14 Participant ID CTP - Site ID **QSDTC** Assessment Date: **USUBJID** m m LEGAL STATUS =QSSCAT OSTEST **QSORRES** L1. Was this admission prompted by the criminal justice Comments: 0-No. 1-Yes system? Judge, probation/parole officer, etc. (X=Not Answered) L2. Are you on parole or probation? 0-No. 1-Yes Note duration and level in comments. (X=Not Answered) How many times in your life have you been arrested and charged with the following: include total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult. Include formal charges only. (XX=Not Answered) L3. Shoplifting/Vandalism L10. Assault Data not entered L4. Parole/Probation Violations L11. Arson L5. Drug Charges L12. Rape L6. Forgery L13. Homicide/Manslaughter L7. Weapons Offense L14. Prostitution L15. Contempt of court L8. Burglary/Larceny/B&E L9. Robbery L16. Other: (specify\_ How many of these charges resulted in convictions? If L3-L16="00", then L17= "NN". Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas. (XX=Not How many times in your life have you been charged with the following: Disorderly conduct, vagrancy, public intoxication? (XX=Not Answered) L19. Driving while intoxicated (DWI)? (XX=Not Answered) L20. Major driving violations? Moving violations: speeding, reckless driving, no license, etc. (XX=Not Answered) QSORRESU=MONTH How many months were you incarcerated in your life? Mos. If Incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the

number in comments. (XX=Not Answered)

Answered)

0=No. 1=Yes

L24. Are you presently awaiting charges, trial, or sentence? (X=Not

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Participant ID CTP - Site ID **QSDTC** Assessment Date: **USUBJID** m m d QSTEST L25. What for? (Refers to L24.) Use code 03-16, 18-20. If more than one, **QSORRES** Comments: choose most severe. Don't include civil cases, unless a criminal offense is involved. (XX=Not Answered, NN= Not Applicable) 03 - Shoplifting 12 - Rape 04 - Probation violation 13 - Homicide 05 - Drug 14 - Prostitution 06 - Forgery 15 - Contempt 07 - Weapons 16 - Other 08 - Burglary 18 - Disorderly conduct 09 - Robbery 19 - DWI **Data not entered** 10 - Assault 20 - Major driving violation 11 - Arson L28. How many days in the past 30, were you detained or incarcerated? OSEVLINT=-P30D OSORRESU=DAY Include being arrested and released on the same day. (XX=Not Answered) L27. How many days in the past 30, have you engaged in illegal activities for profit?QSEVLINT=-P30D QSORRESU=DA Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross- checked with Question E17 under Employment/Family Support Section. (XX=Not Answered) For questions L28 & L29, ask the patient to use the Patient Rating scale. L28. How serious do you feel your present legal problems are? Exclude civil problems. (X=Not Answered) L29. How important to you now is counseling or referral for these legal problems? Patient is rating a need for additional referral to legal counsel for defense against criminal charges. (X=Not Answered) CONFIDENCE RATINGS Is the above information significantly distorted by: L31. Patient's misrepresentation? 0=No. 1=Yes L32. Patient's inability to understand? 0=No. 1=Yes

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CTP - Site ID	Participant ID	Account Bates / CODIC
	<u>USUBJID</u>	Assessment Date: / /QSDTC m m d d y y y y

### FAMILY/SOCIAL RELATIONSHIPS =QSSCAT F1. Marital Status QSTEST **QSORRES** Comments: 1 - Married 3 - Widowed 5 - Divorced 2 - Remarried 4 - Separated 6 - Never Married Common-law marriage = "1." (Specify in comments) (X=Not Answered) F3. Are you satisfied with this situation? (Refers to Question F1) 0=No. 1=Indifferent. Satisfied - generally liking the situation. (X=Not Answered) 2=Yes QSEVLINT=-P3Y F4. Usual living arrangements (past 3 years): 6 - With friends 1 - With sexual partner & children 7 - Alone 2 - With sexual partner alone 3 - With children alone 8 - Controlled Environment 9 - No stable arrangement 4 - With parents 5 - With family Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement. (X=Not Answered) Are you satisfied with these arrangements? 0-No. 1-Indifferent. Refers to response in Question F4. (X=Not Answered) Data not entered 2=Yes Do you live with anyone who: F7. Has a current alcohol problem? (X=Not Answered) 0=No, 1=Yes F8. Uses non-prescribed drugs? (X=Not Answered) 0=No, 1=Yes F9. With whom do you spend most of your free time? 1=Family. If a girifriend/boyfriend is considered as a family by patient, then they must 2-Friends, 3-Alone refer to them as family throughout this section, not a friend. Family is not to be referred to as "friend." (X=Not Answered) F10. Are you satisfied with spending your free time this way? (Refers to Question F9.) 0=No. 1=Indifferent, 2=Yes A satisfied response must indicate that the person generally likes the situation. (X=Not Answered) Have you had significant periods in which you have experienced serious problems getting along with: "Serious problems" mean those that endangered the relationship. A "problem" requires contact of some sort, either by telephone or in person. a. Past b. Life-0= No, 1= Yes, (X= Not Answered, N= Not Applicable) 30 Days time F18. Mother F19. Father F20. Brothers/Sisters F21. Sexual Partner/Spouse F22. Children F23. Other Significant Family (Specify \_\_\_\_\_ F24. Close Friends F25. Neighbors F26. Co-workers

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**QSDTC** 

Assessment Date: **USUBJID** m d d a. Past b. Life-0= No, 1= Yes (X=Not Answered) Comments: 30 Days time QSTEST
Did anyone (Questions F18 - F26) abuse you? QSEVLINT=-P30D **QSORRES** F28. Physically? (Caused you physical harm.) F29. Sexually? (Forced sexual advances/acts.) How many days in the past 30 have you had serious conflict©SEVLINT=-P30D QSORRESU=DAY F30. With your family? (XX= Not Answered) For Questions F32 and F34, ask the patient to use the Patient Rating scale. How troubled or bothered have you been in the past 30 days Data not entered by these: QSEVLINT=-P30D F32. Family problems (X= Not Answered) How important to you now is treatment or counseling for F34. Family problems Patient is rating his/her need for counseling for family problems, not whether the family would be willing to attend. (X= Not Answered) How many days in the past 30 have you had serious conflicts: QSEVLINT=-P30D QSORRESU=DAY F31. With other people (excluding family)? (XX=Not Answered) For Questions F33 and F35, ask the patient to use the Patient Rating scale. How troubled or bothered have you been in the past 30 days by these: QSEVLINT=-P30D F33. Social problems (X= Not Answered) How important to you now is treatment or counseling for these: F35. Social problems include patient's need to seek treatment for such social problems as ioneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if patient had no substance abuse. (X= Not Answered) CONFIDENCE RATING Is the above information significantly distorted by: F37. Patient's misrepresentation? 0-No. 1-Yes F38. Patient's inability to understand? 0=No. 1=Yes

Participant ID

ASL

CTP - Site ID

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I	CTP - Site ID	Participant ID	Assessment Date:		/	/	QSDTC			3	1	
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### PSYCHIATRIC STATUS = QSSCAT

	QSTEST	
	How many times have you been treated for any psychological or emotional problems:	Comments:
	Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in comments if known.	
QSORRES	P1. In a Hospital or inpatient setting? (XX= Not Answered)	
	P2. Outpatient/private patient? (XX= Not Answered)	
0=No. 1=Yes	P3. Do you receive a pension for a psychiatric disability? (X=Not Answered)	
2,		Data not entered
	Have you had a significant period of time (that was not a direct result of alcohol/drug use) in which you have:	
a. Past b. Life- 30 Days time	0=No, 1=Yes, (X= Not Answered)	
QSEVLINT=-P30D	P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	
	P5. Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?	
	P6. Experienced hallucinations-saw things or heard voices that other people did not see or hear?	
	P7. Experienced trouble understanding, concentrating, or remembering?	
	For questions P8-P10, patient could have been under the influence of alcohol/drugs.	
	P8. Experienced trouble controlling violent behavior including episodes of rage, or violence? (Patlent can be under the Influence of alcohol/drugs.)	
	<ol> <li>Experienced serious thoughts of suicide? Patient seriously considered a plan for taking his/her life.</li> </ol>	
	P10. Attempted suicide? (Include actual suicidal gestures or attempts.)	
	P11. Been prescribed medication for any psychological or emotional problems? (Prescribed for the patient by MD. Record "Yes" If a medication was prescribed even if the patient is not taking it.)	
	P12. How many days in the past 30 have you experienced these psychological or emotional problems? (This refers to problems noted in Questions P4-P10.) (XX= Not Answered)	
	OSEVLINTP30D OSORRESH-DAY	

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Is the above information significantly distorted by:

P22. Patient's misrepresentation?

P23. Patient's inability to understand?

0=No, 1=Yes

0=No, 1=Yes

Participant ID CTP - Site ID **QSDTC** Assessment Date: m m **USUBJID** d For Question P13 & P14, ask the patient to use the Patient Comments: Rating scale. QSORRES Rating scale. QSTEST P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? (Patlent should be rating the problem days from Question P12.) (X= Not Answered) QSEVLINT=-P30D P14. How important to you now is treatment for these psychological or emotional problems? (X= Not Answered) CONFIDENCE RATING

**Data not entered** 

ADDENDUM TO ASI-LITE (ADD) QSCAT=ASI ADDENDUM FOR WOMEN

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NIDA-CTN-0015	Women's Trea	Seq. Num.:						
NODE:				EPOC				
CTP-SITE ID:		_	STUDY Visit: (circle one)	VISITN		seline		
PARTICIPANT ID:	_USUBJID	_						
Assessment Date:	/	_ /	QSDTC (	mm / dd / yyyy)	STAFF	ID:	QSEVAL	
FORM COMPLETION STATUS			2=Participant refused 5-			4-Not enough time to Administer 5-No Participant Contact 6-Other		

(Independent Assessor Completed)

NA

Yes No

A. When did you first enroll in a treatment program at this clinic? \_\_\_ / \_\_ / \_\_ / \_\_ (mm/dd/yyyy)

Recruitment/Screening Sources

	QSORRES			Are you currently under pressure to come to or stay in sources? QSTEST	treatment from the following
1	0	-9	1a.	An employer, school, or training program	
1	0	-9	1b.	Your lawyer	
1	0	-9	1c.	A court, parole, or probation officer, or other part of the crim	ninal justice system
1	0	-9	1d.	A housing or other community agency	
1	0	-9	1e.	Your church or close friend	
1	0	-9	1f.	Your spouse, partner, or family	
1	0	-9	1g.	Department of Children and Family Services (Child Protecti	on Services agency)
1	0	-9	1h.	Other source (If yes, specify below in question 1i.)	
			1i.	Other source (specify):	
Yes	No	NA		Reproductive Health Questions	
			2.	When you first started having your period, how old were yo	u?
1	0	-9	3.	Have you ever been pregnant? (If no or not answered, skip with question 4.)	to question 13a. If yes, continue
			4.	How old were you when you became pregnant for the first t	ime?
			5.	How old were you when you became pregnant for the last t	ime/most recent time?
			6.	How many times have you been pregnant?	
1	0	-9	7a.	Were any babies born alive but later died? (If yes, ask ques to question 8a.)	tion 7b. If no or not answered, skip
			7b.	If yes, how many?	
1	0	-9	8a.	Have you had any abortions? (If yes, ask question 8b. If no 9a.)	or not answered, skip to question
			8b.	If yes, how many?	
1	0	-9	9a.	Have you had any miscarriages? (If yes, ask question 9b. If question 10a.)	no or not answered, skip to
			9b.	If yes, how many?	
1	0	-9	10a.	Did you ever have a stillbirth? (If yes, ask question 10b. If no 11a.)	o or not answered, skip to question
			10b.	If yes, how many?	
1	0	-9	11a.	Were any babies born prematurely and survived? (If yes, as answered, skip to question 12a.)	sk question 11b. If no or not
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CTP - Site ID	Participant ID	Assessment Date:			/		, Q	SDT	С	
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Yes	No	NA		Reproductive Health Questions (continued)
QS	ORRE	S	11b.	If yes, how many? QSTEST
1	0	-9	12a.	Did you use any drugs during <u>any</u> pregnancies (does not include prescribed medication, e.g., methadone)? (If yes, ask question 12b. If no or not answered, skip to question 13a.)
		_	12b.	Was it during all of the pregnancies <u>or</u> some of the pregnancies?  1 – All 2 – Some of the pregnancies
1	0	-9	13a.	Have you gone through menopause (or already experienced the change of life)? (If no or not answered, ask question 13b. If yes, skip to question 14a.)
1	0	-9	13b.	If no, are you currently in menopause?
Yes	No	NA		Legal
				Do you have any legal problems involving your family (i.e., the members of your household), such as?
1	0	-9	14a.	Family or juvenile court?
1	0	-9	14b.	Child custody involving DHS?
1	0	-9	14c.	Divorce?
1	0	-9	14d.	Domestic violence?
1	0	-9	14e	Department of immigration?
1	0	-9	14f.	Other (If yes, specify below in question 14g.)
			14g.	Other (specify):
Yes	No	NA		Family/Social
1	0	-9	15.	Have you ever been homeless or not had a permanent place to live?
1	0	-9	16a.	Do you have any children living with you? (If yes, ask questions 16b thru 17p. If no or not answered, skip to question 18a.)
		_	16b.	Have your children usually been living with you in the past three years?  1 - Yes, all 2 - Yes, some 3 - No, none
			16c.	How many children live in your household?
			16d.	How many of those are your biological children?
				Is there anyone who helps you on a regular basis to take care of your children who are living with you (e.g., babysitting, preparing meals, feeding kids, bathing, dressing children)?  (Circle yes or no for each teem.)
1	0	-9	17a.	Child's biological mother?
1	0	-9	17b.	Child's biological father?
1	0	-9	17c.	Child's stepmother?
1	0	-9	17d.	Child's stepfather?
1	0	-9	17e.	Foster mother?
1	0	-9	17f.	Foster father?
1	0	-9	17g.	Child's brother/sister?
1	0	-9	17h.	Client's sex partner/spouse?
1	0	-9	17i.	Child's grandmother?
1	0	-9	17j.	Child's grandfather?
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_	CTP - Site ID			Participant ID USUBJID	Assessment Date: / / QSDTC y y y y
Yes	No	NA		Family/Social (continued)	
1	0	-9	17k.	Client's GM/GF? QS	STEST
1QS	SORRES	-9	171.	Other significant family?	
1	0	-9	17m.	Close friends?	
1	0	-9	17n.	Neighbors?	
1	0	-9	17o.	Other clients?	
1	0	-9	17p.	Other? (If yes, specify below i	in question 17q.)
			17q.	Other (specify):	
Yes	No	NA			
1	0	-9	18a.		<ol> <li>has anyone used physical violence (such as being slapped, e threat of physical violence against you? (If yes, ask questions skip to question 19a.)</li> </ol>
				If yes, how was this person	related to you:
1	0	-9	18b.	Spouse ?	
1	0	-9	18c.	Other family member?	
1	0	-9	18d.	Partner/significant other?	
1	0	-9	18e.	Stranger?	
1	0	-9	18f.	Did you receive medical treat	ment for any injuries as a result of physical violence against you?
Yes	No	NA			
1	0	-9	19a.	As an adult, has anyone used of sexual violence against you question 20a.)	d sexual violence (forcing you to do anything sexual) or the threat u? (If yes, ask questions 19b-19f. If no or not answered, skip to
				If yes, how was this person	related to you:

				question 20a.)
				If yes, how was this person related to you:
1	0	-9	19b.	Spouse?
1	0	-9	19c.	Other family member?
1	0	-9	19d.	Partner/significant other?
1	0	-9	19e.	Stranger?
1	0	-9	19f.	Did you receive medical treatment for any injuries as a result of sexual violence against you?
1	0	-9 -9 -9	19c. 19d. 19e.	Other family member? Partner/significant other? Stranger?

Yes	No	NA		
1	0	-9	20a.	When you were a child (under the age of 18), did anyone ever use physical violence (like doing something on purpose that gave you bruises, broke bones or made you bleed) or the threat of violence against you? (If yes, ask questions 20b-20f. If no or not answered, skip to question 21a.)
				If yes, how was this person related to you:
1	0	-9	20b.	Parent?
1	0	-9	20c.	Other family member?
1	0	-9	20d.	Partner/significant other?
1	0	-9	20e.	Stranger?

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•	CTP - Site ID	Participant ID	Assessment Date:	_ / _		/	QSDT	С	
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Yes	No	NA .	221	QSTEST
1	0	-9	20f.	Did you receive medical treatment for any injuries as a result of physical violence against you?
C	SORRI	ES		
Yes	No	NA		
1	0	-9	21a.	When you were a child (under the age of 18), were you ever the victim of sexual abuse or sexual assault or engaged in any sexual activity against your will, like someone touching you sexually or making you do sexual things that you did not want, etc? (If yes, ask questions 21b-21f. If no or not answered, skip to question 22.)
				If yes, how was this person related to you:
1	0	-9	21b.	Parent?
1	0	-9	21c.	Other family member?
1	0	-9	21d.	Partner/significant other?
1	0	-9	21e.	Stranger?
1	0	-9	21f.	Did you receive medical treatment for any injuries as a result of sexual violence against you?
				Overall Health
		_	22.	Please rate your current health status in general:  1 = Excellent 2 = Good 3 = Fair 4 = Poor 5 = Very poor -9 = Not answered
				Please tell me how much you agree or disagree with the following statements:
		_	23.	I am somewhat ill.  1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
		_	24.	I am as healthy as anybody I know.  1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
		_	25.	My health is excellent.  1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
		_	26.	I have been feeling bad lately.  1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered

RISK BEHAVIOR SURVEY (RBS)		QSCA I =RISK BEHAVIORS SURVEY	ORVEY	DO	DOMAIN: QS	PAGE 1 OF 3
NIDA-CTN-0015	Women's STUDYID	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial	Substance Use D cal Trial	isorders:	Seq. Num.:	lum.:
NODE:			ЕРОСН	Race	Raceline	VISITNUM
CTP-SITE ID:	USUBJID 	STUDY Visit: (circle one)				Si di
PARTICIPANT ID:			WK-FOF	S-Month FOR	3-Month FOF G-Month FOF 12-Month FOF	12-Month FUP
Assessment Date:	Date: /QSDTC	7TC (mm / dd / yyyy)		STAFF ID:	FID:	QSEVAL
FORM COMPLETION STATUS	TION STATUS	1-CRF Administered 2-Participant refused 3-Staff Member did not Administer	4-Not enough time to Administer 5-No Participant Contact 6-Other	ne to Administer Contact		

(Independent Assessor Completed)

The RBS contains sensitive information on drug use and sexual behavior. Please ensure that you have developed rapport with the participant before asking these questions. QSEVLINT=-P30D INTERVIEWER:

QSSCAT = DRUG USE A. DRUG USE

OSTEST a.	I'm going to ask you some (I'no use, skip to next questions about your drug use. I'll ask what types of drugs you've used and how often you use them.	NO YES	Cocaine by itself (injected or snorted)	Heroin by itself 0 1	Heroin & Cocaine 0 1 (Speedball)	Other Opiates (Demerol, Codeine, 0 1 Dilaudid)	Amphetamines (Speed, 0 1
	ver used: kip to next gj) RES	UNK REF	9 7	9 7	9 7	9 7	9 7
p.	How many days did you use in the last 30 days? (if 00, do not ask parts c- f, and skip to next drug)	F OSOBBESIL DAV					
С.	How many days did you inject in the last 30 days? (if 00, skip to parr e)						
d.	How many times a day did you inject ? (Avarage # of injections/day)						
e,	How many days did you How many times a use without injecting day did you use (smoking, snorting, without swallowing) in the last 30 injecting? days? class		QSORRESU=DAY 				
ť.	How many times a day did you use without injecting?						

QSCAT=RISK BEHAVIOR SURVEY (RBS)

DOMAIN: QS

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KDS	, ,							FA	GE 4	4 UF ,
CTP - Site ID	Participant ID	Assessment Date:					/ _ <u>C</u>	SD	TC	
			m	m	d	d	у	у	y	у

B.	DRUG	i IN	JEC.	TION (if no in	=QSSCAT jection use in j	DRUG INJECTI past 30 days, skip t	ON o Section C)		
QS	ORRES	1.	Q In the that y	STEST a last 30 days,	how many tim been used by		) did you inject using wo	QSEVLINT=-P30I orks (needle/syringes)	D
		2.					times did you clean the d after a friend (qB1).)	works with full-strength	
		3.		many times in ner injector?	the last 30 da	ys did you use a c	ooker/cotton/rinse wate	r that had been used by	
		4.					s with another person, t hrough front or back loa		
C.	SEXU	ΑL	ACT	IVITY	QSSC	AT=SEXUAL AC	CTIVITY		
		_	_	ask you some			ng here to anybody you	've had sex with in the	
	last 30			on the last 30 d	lavs with how	many people did y	ou have vaginal, oral o	r anal sav?	
/IF NON	 F FNTFD			THE QUESTIONN	•		you have vaginal, oral o	aliai sex:	
(a reon	L, LIVIER			-		•	nnot exceed total number	of people (nC1))	
							not exceed total number of		
							ial events and condor		
		_			g				
				cy scale: regularly	01		Condom/Barrier use Never	0	
				once a week	02		Less than half the time	1	
				e a week	03		About half the time	2	
				a week e a day	04 05		More than half the time	3	
			times		06		Always Don't know/unsure	9	
				times a day	07		Refused	7	
			n't knov jused	w/unsure	99 77				
_	-	(IT N	tale, co	viewer: Code g implete sections complete section	D, E, F, G & I)	ondent (1=Male	e, 2=Female, 9=Don't Kno	w)	
				-		c guestions and allow	client to answer as they lik	e)	
D.	Ask N							FEMALE PARTNER	
-		1.a		-	-	oral sex ("went do			
		(IF O					nber of female partners (qC	"	
							k ("go down") on you? (		
			1.c		•	doms/dental dams /barrier use scale)	when your partner(s) p	erform oral sex ("went	
_		2.a	H	low many won	nen did you pe	erform oral sex ("go	down") on?		
			mers (c	(C2))			lent. Number cannot exceed		
			2.b				") on your partner(s)? (		
			2.c		-	doms/dental dams v/barrier use scale)	when you performed or	ral sex ("went down") on	
								<u> </u>	

Modified: 9/15/2003

QSCAT=RISK BEHAVIOR SURVEY DOMAIN: QS RBS PAGE 3 OF 3 CTP - Site ID Participant ID Assessment Date: USUBJID Condom/Barrier use scale: Frequency scale: Once or irregularly 01 Never n Less than once a week 02 Less than half the time 1 About once a week 03 About half the time 2 2-8 times a week 04 More than half the time 3 05 About once a day Always 4 2-3 times a day 06 Don't know/unsure 9 4 or more times a day 07 Refused Don't know/unsure 77 QSSCAT=SEXUAL ACTIVITY - MALE CLIENT WITH FEMALE PARTNER Refused OSEVLINT=-P30D E. Ask Male Clients who had Female Partners: How many women did you have vaginal sex with? QSTEST (If 000, then skip to question 2a. Number cannot exceed total number of female partners (qC2)) How often did you have vaginal sex? (Use frequency scale) How often did you use a condom? (Use condom/barrler use scale) How many women did you have (insertive) anal sex with? (If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of fe<mark>male</mark> partners (qC2)) 2.b How often did you have (insertive) anal sex? (Use frequency scale) How often did you use a condom? (Use condom/barrier use scale) (UAL ACTIVITY F. Ask Male Clients who had Male Partners: How many men did you have (insertive) anal sex with? (If 000, then skip to next section appropriate for the sex of this cilent. Number cannot exceed total number of male partners (qC3)) 1.b How often did you have (insertive) anal sex? (Use frequency scale) How often did you use a condom? (Use condom/barrier use scale) QSSCAT=SEXUAL ACTIVITY Ask Male/Female Clients who had Male Partners G. How many men performed oral sex ("went down") on you? (If 000, then skip to question 2a. Number cannot exceed total number of male partners (qC3)) How often did your partner(s) perform oral sex ("go down") on you? (Use frequency scale) How often did you use condoms/dental dams when your partner(s) perform oral sex ("went down") on you? (Use condom/barrier use scale) How many men did you perform oral sex ("go down") on? (If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3)) 2.b How often did you perform oral sex ("go down") on your partner(s)? (Use frequency scale) How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)? (Use condom/barrier use scale) Ask Female Clients who had Male Partners: OSSCAT-SEXUAL ACTIVITY H. How many men did you have vaginal sex wifeEMALE CLIENT WITH MALE PARTNER (If 000, then skip to next section appropriate for the sex of this client Number cannot exceed total number of male parmers (qC3)) How often did you have vaginal sex? (Use frequency scale) How often did you use a condom? (Use condom/barrier use scale) Ask Male/Female Clients who had Male Partners OSSCAT-SEXUAL ACTIVITY How many men did you have (receptive) anal sex with ENT WITH MALE PARTNER (If 000, end questionnaire. Number cannot exceed total number of male partners (qC3))

1 b

How often did you have (receptive) anal sex? (Use frequency scale)

How often did you use a condom? (Use condom/barrier use scale)

DOMAIN: TU

### NON-STUDY MEDICAL SERVICES - FOLLOW-UP (NSMF)

PAGE 1 OF 1

NIDA-CTN-0015	Women's Treatn	nent For Trauma A A Randomized (		e Use Disorders:	Seq. Num.:	
NODE:						
CTP-SITE ID:		STUDY Visit: (circle one)	3-Month F			
PARTICIPANT ID:	USUBJID			EPOCH	VISITNUM	
Assessment Date:	Assessment Date: / / / / (mm / dd / yyyy)					
FORM COMPLE	TION STATUS	1-CRF Administered 4-Not enough time to 2-Participant refused 5-No Participant Con 3-Staff Member did not Administer 6-Other			dminister t	

(Independent Assessor Completed)

#### TUTEST/TUTESTCD

A. When did the participant last complete this form?

1	- /	TUOR	RES <sub>mm/dd/y)</sub>	rvv)

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We'd like you to answer these questions for the medical services you've received including those that are part of this outpatient program (but excluding those associated with this study).

Yes	No		In the past	30 days, have you	TUEVLINT=-P30D
1 TUOR	0 RES	1a.		oist, that is a psychiatrist, psychologist, counselo , or emotional problems? (If no or not answered, the	r, or social worker for drug,
1001	ITTE	1b.	TUORRES	(If YES), how many times did you see a psychia	trist or psychologist?
		1c.		(If YES), how many times did you see a counse	lor or social worker?
1	0	2a.		ical office, not including your therapist? (Include oner, or physician's assistant) (If no or not answered	
		2b.		(If YES), how many visits to a medical office has	ve you had?
		2c.		(If YES), how many of these visits did you see a	doctor?
1	0	За.		d into a residential program to detoxify or for othe sizion 4a, below)	er services? (If no or not answered,
		3b.		(If YES), how many admissions?	
		3c.		(If YES), how many nights for all stays?	
1	0	4a.	Been admitte	d into a hospital to detoxify? (If no or not answered,	then skip to question 5a, below)
		4b.		(If YES), how many admissions?	
		4c.		(If YES), how many nights for all stays?	
1	0	5a.	Been admitte below)	d to the hospital for any other reason? (If no or no	ranswered, then skip to question 6a,
		5b.		(If YES), how many times were you admitted?	
		5c.		(If at least once), how many nights for all stays?	
1	0	6а.	Visited an em to question 7a,	ergency room and not been admitted to the hosp below)	oital? (If no or not answered, then skip
		6b.		(If YES), how many times did you visit the emer	gency room?
1	0	7a.	Attended any	12-step or self – help meetings? (If no or not answ	ered, then end interview)
		7b.		(If YES), how many times did you attend 12-ste	p or self – help meetings?

STUDYID

**DOMAIN: QS** 

PAGE 1 OF 3

NIDA-CTN-0015	Women's Trea	tment For Trauma A A Randomized (		Use Disorders:	Seq. Num.:	
NODE:				Baseline	VISITNUM	
CTP-SITE ID:		STUDY Visit: (circle one)	STUDY Visit: , (circle one)		Ionth FUP EPOCH	
PARTICIPANT ID:	USUBJID		6	3-Month FUP 12-N	Month FUP	
Assessment Date:	/	/ QSDTC (	mm / dd / yyyy)	STAFF ID:	QSEVAL	
FORM COMPLE	ETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did no				

(Independent Assessor Completed)

INSTRUCTIONS: On the next page is a list of problems people sometimes have. Please read each one carefully, and circle the number that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY. Circle only one number for each problem and do not skip any items. If you change your mind, cross out the incorrect circle with an 'X' and circle the correct response. Read the example before beginning, and if you have any questions please ask them now.

#	EXAMPLE  QSTEST  How much were you distressed by:	Notatall	A little bit	Moderately	Quite a bit	Extremely
1	Bodyaches	0	1	2	3	4

**QSORRES** 

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BSI =QSCAT PAGE 2 OF 3

				ORRES	tely	bit	ely
#	QSTEST How much were you distressed by:		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Nervousness or shakiness inside		0	1	2	3	4
2	Faintness or dizziness		0	1	2	3	4
3	The idea that someone else can control your thoughts	1	0	1	2	3	4
4	Feeling others are to blame for most of your troubles	T	0	1	2	3	4
5	Trouble remembering things		0	1	2	3	4
6	Feeling easily annoyed or irritated	Т	0	1	2	3	4
7	Pains in heart or chest		0	1	2	3	4
8	Feeling afraid in open spaces or on the streets		0	1	2	3	4
9	Thoughts of ending your life		0	1	2	3	4
10	Feeling that most people cannot be trusted		0	1	2	3	4
11	Poor appetite		0	1	2	3	4
12	Being suddenly scared for no reason	T	0	1	2	3	4
13	Temper outbursts that you could not control		0	1	2	3	4
14	Feeling lonely even when you are with people	T	0	1	2	3	4
15	Feeling blocked in getting things done		0	1	2	3	4
16	Feeling lonely	T	0	1	2	3	4
17	Feeling blue		0	1	2	3	4
18	Feeling no interest in things	T	0	1	2	3	4
19	Feeling fearful		0	1	2	3	4
20	Your feelings being easily hurt		0	1	2	3	4
21	Feeling that people are unfriendly or dislike you		0	1	2	3	4
22	Feeling inferior to others	)SEV	IIII	=-P7D	2	3	4
23	Nausea or upset stomach	YOL V	LIIVI	1 70	2	3	4
24	Feeling that you are watched or talked about by others		0	1	2	3	4
25	Trouble falling asleep		0	1	2	3	4
26	Having to check and double-check what you do		0	1	2	3	4
27	Difficulty making decisions		0	1	2	3	4
28	Feeling afraid to travel on buses, subways, or trains		0	1	2	3	4
29	Trouble getting your breath		0	1	2	3	4
30	Hot or cold spells		0	1	2	3	4
31	Having to avoid certain things, places, or activities because they frighten you		0	1	2	3	4
32	Your mind going blank		0	1	2	3	4
33	Numbness or tingling in parts of your body		0	1	2	3	4

#	QSTEST How much were you distressed by:	Not at all	QSORRES Hutte Hutte V	Moderately	Quite a bit	Extremely
34	The idea that you should be punished for your sins	8	1	2	3	4
35	Feeling hopeless about the future	0	1	2	3	4
36	Trouble concentrating	0	1	2	3	4
37	Feeling weak in parts of your body	0	1	2	3	4
38	Feeling tense or keyed up	0	1	2	3	4
39	Thoughts of death or dying	0	1	2	3	4
40	Having urges to beat, injure, or harm someone	0	1	2	3	4
41	Having urges to break or smash things	0	1	2	3	4
42	Feeling very self-conscious with others	0	1	2	3	4
43	Feeling uneasy in crowds, such as shopping or at a movie	QS <mark>E</mark>	VLINT=-P7D	2	3	4
44	Never feeling close to another person	0	1	2	3	4
45	Spells of terror or panic	0	1	2	3	4
46	Getting into frequent arguments	0	1	2	3	4
47	Feeling nervous when you are left alone	0	1	2	3	4
48	Others not giving you proper credit for your achievements	0	1	2	3	4
49	Feeling so restless you couldn't sit still	0	1	2	3	4
50	Feelings of worthlessness	0	1	2	3	4
51	Feeling that people will take advantage of you if you let them	0	1	2	3	4
52	Feelings of guilt	9	1	2	3	4
53	The idea that something is wrong with your mind	0	1	2	3	4

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FOR BASELINE AND FOLLOWILD.

#### **STUDYID**

### POST-TRAUMATIC SYMPTOM SELF REPORT (PSSR) = QSCAT

PAGE 1 OF 1

NIDA-CTN-0015	Women's Tre			na And Substance Use Disorders: ed Clinical Trial Seq. Num.:		
NODE:			STUDY	2020	eline Wk1v1 Wk1v2	
CTP-SITE ID:			Visit: (circle one)	Wk3v1 Wk6v	Wk3v2 Wk4v1 Wk v1 Wk6v2 1-WkFL	
PARTICIPANT ID:	USUBJI	D_	(====,	EPOCH	Month FUP VISITNUM	
Assessment Date: / /			/ QSDTC (mm / dd / yyyy) STAFF ID:			QSEVAL
FORM COMPLETION STATUS			RF Administered articipant refused taff Member did not	t Administer	4-Not enough time to Adn 5-No Participant Contact 6-Other	ninister

(Research Assistant/Independent Assessor Completed)

FREQUENCY SCALE:

#### THESE QUESTIONS REFER TO YOUR TRAUMATIC EVENT(S).

This scale measures the frequency and severity of symptoms since your last visit.\* For each symptom, please indicate the <u>FREQUENCY and SEVERITY</u> by entering the appropriate code from the table below. If a symptom did not occur at all (Frequency=1) during the assessment period, then code the Severity as 'not at all' (code 1).

\*For the Baseline and Follow-Up assessments, the participant should consider her symptoms in the past 7 days. During the Treatment Phase of the study, she should consider the symptoms since her last visit.

SEVERITY SCALE:

INCA	OLNOT SCALL.	SEVERIT SCALE.	FOR BASELINE AND	FOLLOWUŁ	): :
2=One 3=2-4	t at all ce a week times per week/Half the time	ALL VARIABLES			
4=5 o	r more times per week/Almost always	4=Quite a bit 5=Extremely		(a)	(b)
	QSTEST			FREQUENCY	SEVERITY
1	Having upsetting thoughts or image want them to.	es about the trauma th	at came into your head when you didn't	QSOI	RRES
2	Having bad dreams or nightmares	about the trauma.			
3	Reliving the trauma, acting or feeling	ng as if it was happenir	ig again.		
4	Feeling emotionally upset when yo angry, sad, guilty, etc.).				
5	Trying not to think about, talk abou				
6	Trying to avoid activities, people, or places that remind you of the trauma.				
7	Not being able to remember an imp				
8	Having less much less interest or p	articipating much less	often in important activities.		
9	Feeling distant or cut off from peop	le around you.			
10	Feeling emotionally numb (for exar	mple, being unable to o	ry or unable to have loving feelings).		
11	Feeling as if future plans or hopes children, or long life).	will not come true (for	example, will have no career, marriage,		
12	Having trouble falling or staying as	leep.			
13	Feeling imitable or having fits of an	ger.			
14	Having trouble concentrating (for e story on television, forgetting what		out of conversations, losing track of a		
15	Being over-alert (for example, chec back to the door, etc.).	king to see who is aro	und you, being uncomfortable with your		
16	Being jumpy or easily startled (for e	example, when someor	ne walks up behind you).		
17	Experiencing PHYSICAL reactions out in a sweat, heart beating fast).	when you were remind	ded of the trauma (for example, breaking		

SUBSTANCE U	SE IN	VENTORY (SUI	) =QSCAT	STUDYID	DOMAIN:	QS PAGE 1 OF 3
Women's Treatment For Trauma And Substance Use Disorders:						Seq. Num.:
NOD	E: _				e Wk1v1 Wk1v2	
CTP-SITE ID:			STUDY Visit: (circle one)	Wk3v1 Wk3v2 Wk4v1 Wk4v2 Wk5v1 Wk5v Wk6v1 Wk6v2 1-Wk FUP 3-Month FUP		
PARTICIPANT ID:		USUBJID		EPOCH <sup>6</sup>	Ionth FUPVISITNUM	
Assessment Da	ite:	//	QSDTC (n			QSEVAL
FORM COMPLETION STATUS  1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 5-No Participant Contact 6-Other						
(Research Assistant/Independent Assessor Completed)  QSTEST FOR BASELINE AND FOLLOWUP:  (RA/IA will complete Q1.) QSEVLINT = -P7D FOR ALL VARIABLES  1. When did the participant last complete this form?/_ QSORRES_						L VARIABLES
	(mm/dd/yyyy)  (For baseline and follow-up assessments, leave question 1 blank and ask the participant to evaluate her substance use in the past 7 days. For treatment phase assessments, the participant should evaluate her substance use between the day before the current day, and the date of her last visit, indicated in question 1.)					
	ALCO	OHOL USE				
QSORRES	2a. 2b.	Number of days	QSSCAT on which alcohol v of drinks <u>per day</u>	vas used (If 0 or	r not answered, skip to	QSORRESU=DAYS
	2c.	Maximum dollar value of alcohol used in one day  OSORRESU=1				RRESU=DOLLARS

		QUILUI TOR BRIBELINE FIND TOLLOW OT:
		(RA/IA will complete Q1.) QSEVLINT = -P7D FOR ALL VARIABLES
	1.	When did the participant last complete this form?/_QSORRES
		(For baseline and follow-up assessments, leave question 1 blank and ask the participant to evaluate her substance use in the past 7 days. For treatment phase assessments, the participant should evaluate her substance use between the day before the current day, and the date of her last visit, indicated in question 1.)
	ALCO	OHOL USE
QSORRES	2a.	=QSSCAT Number of days on which alcohol was used (If 0 or not answered, skip to @200)
	2b.	Average number of drinks per day  QSORRESU=DAYS
	2c.	Maximum dollar value of alcohol used in one day  QSORRESU=DOLLARS
		(Answer Q.2d and Q.2e, even if there is no alcohol use at all.)
	2d.	Number of days on which urge, desire or craving for alcohol occurred QSORRESU=DAYS
	2e.	How strong was the urge? How hard was it to resist?  0 = None
		1 = Mild urges, easily resisted
		2 = Moderate urges, requiring effort to resist
		3 = Strong urges to use, difficult to resist 4 = Severe, usually impossible to resist urges to use
	COCA	AINE USE =QSSCAT
	3a.	Number of days on which cocaine was used (If 0 or not answered, skip to Q.3e)  QSORRESU=DAYS
	3b.	Average dollar value of cocaine used per day
	30.	QSORRESU=DOLLARS
	3c.	Maximum dollar value of cocaine used in one day  QSORRESU=DOLLARS
	3d.	Principal route of cocaine use:
		1 = Oral
		2 = Inhaled 3 = Smoked (freebase/crack)
		4 = Non-I.V. injection
		5 = I.V.
		6 = Other
		(Answer Q.3e and Q.3f, even if there is no cocaine use at all.)
	3e.	Number of days on which urge, desire or craving for cocaine occurred

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		QSTEST	
	3f.	How strong was the urge? How hard was it to resist?  0 = None	•
		1 = Mild urges, easily resisted 2 = Moderate urges, requiring effort to resist 3 = Strong urges to use, difficult to resist	
		4 = Severe, usually impossible to resist urges	to use
QSORRES	HERO	DIN USE =QSSCAT	
	4a.	Number of days on which heroin was used (If 0 or not	answered, skip to Q.4e)QSORRESU=DAYS
	4b.	Average dollar value of heroin used per day	QSORRESU=DOLLARS
	4c.	Maximum dollar value of heroin used in one day	QSORRESU=DOLLARS
	4d.	Principal route of heroin use:	
		1 = Oral	
		2 = Inhaled	
		3 = Smoked (freebase) 4 = Non-I.V. injection	
		5 = I.V.	
		6 = Other	
		(Answer Q.4e and Q.4f, even if there is no heroin use a	t all.)
	4e.	Number of days on which urge, desire or craving for	heroin occurred QSORRESU=DAYS
	4f.	How strong was the urge? How hard was it to resist?	,
		0 = None	
		1 = Mild urges, easily resisted	
		2 = Moderate urges, requiring effort to resist	
		3 = Strong urges to use, difficult to resist 4 = Severe, usually impossible to resist urges to	to use
	MARI	JUANA USE =QSSCAT	
	5a.	Number of days on which marijuana was used (If 0 or	not answered, skip to QSORRESU=DAYS
	5b.	Average dollar value of marijuana used per day	QSORRESU=DOLLARS
	5c.	Maximum dollar value of marijuana used in one day	QSORRESU=DOLLARS
	5d.	Principal route of marijuana use:	
	ou.	1 = Smoked	
		2 = Oral	
		3 = Other	

**DOMAIN: QS STUDYID** 

SUI =QSCAT PAGE 3 OF 3 CTP - Site ID Participant ID Assessment Date: \_\_\_ / \_\_ d \_\_\_ **QSDTC USUBJID** 

		QSTEST (Answer Q.5e and Q.5f, even if there is no marijuana use at all.)
QSORRES	5e.	Number of days on which urge, desire or craving for marijuana occurred QSORRESU=DAYS
	5f.	How strong was the urge? How hard was it to resist?  0 = None  1 = Mild urges, easily resisted  2 = Moderate urges, requiring effort to resist  3 = Strong urges to use, difficult to resist  4 = Severe, usually impossible to resist urges to use
	Any C	Other Drug: Number of Days of Use of Each of the Following: =QSSCAT
	6a.	Other sedatives/hypnotics
	6b.	Stimulants
	6c.	PCP (angel dust)
	6d.	Hallucinogens
	6e.	Any other Drug (Specify drug in Q.6e1, below. If 0 or not answered, skip to Q.6f.)
	6e1.	Other drug used specified:(maximum 200 characters)  (Answer Q.6f and Q.6g, even if there is no other drug use at all. When answering 6f and 6g, think about the substance in 6a thru 6e that was used most often.)
	6f.	Number of days on which urge, desire or craving for any other drug (ccurred SORRESU=DAYS
	6g.	How strong was the urge? How hard was it to resist?  0 = None  1 = Mild urges, easily resisted  2 = Moderate urges, requiring effort to resist  3 = Strong urges to use, difficult to resist  4 = Severe, usually impossible to resist urges to use
	Sumn	nary Drug Use: =QSSCAT
	7a.	Number of days using any illicit drugs or alcohol QSORRESU=DAYS
	7b.	Number of days using any IV or SC (subcutaneous injection) drugs QSORRESU=DAYS
	7c.	Number of days having the urge, desire or craving for any drug  QSORRESU=DAYS
	7d.	How strong was the urge? How hard was it to resist?  0 = None  1 = Mild urges, easily resisted  2 = Moderate urges, requiring effort to resist  3 = Strong urges to use, difficult to resist  4 = Severe, usually impossible to resist urges to use

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**DOMAIN: AE** 

ADVERSE EVENTS (AE)

**STUDYID** 

PAGE 1 OF 2

			A Kandonnized C	annicai iriai		ocq.	14dili
NODE	:				ne Wk1v1 W		
CTP-SITE ID	:		STUDY Visit: (circle one)				k5v1 Wk5v2 IP 6-Month FUP
THE THE PARTY OF T							
Assessment Date	:		AEDTC (m	m / dd / yyyy)	STAFF	ID:	
FORM COM	PLETI	ON STATUS	1=CRF Adminis 2=Participant re 3=Staff Member			ough time to A ticipant Conta	
(Research Assistant/	Indepe	ndent Assesso					
				I		I	
_	1.	0=No (End qu	ant have any new restionnaire)				
AESPID	2.	1=Yes AE Number		HEN NO REC			
	3.	AE Term (Brief		AETERM (AED	DECOD, AE	BODSYS	)
					YKIARA AF	SEVICE C	
_	4a.	Change in seve 0=No (Skip to 1=Yes	erity of previously question 5)	reported AE?	NAM = AE LABEL = A DVAR = AE	AE SEVER	ITY CHANGE
	4b.	(If Yes) Previou	ıs AE Number:		ı		
AESER	5.	Serious* 0=No 1=Yes					AEPRVNUM = PREVIOUS BER
	6a.	Onset Date	, AEST	DTC <sub>(mm/dd/yy)</sub>	уу)	IDVAR =	AESEQ
	6b.	Onset Time AE	STDTC (hh:mn	n, 24-hour cloc	k)		
AE <u>SE</u> V		Severity 1=Mild 2=Moderate 3=Severe					
AEREL	8.	Study Related?	,				
AEACN		0=No 1=Yes					
_	9.	Action Taken 1=None 2=Stop Treatn 3=Other Medic 4=Medical Car 5=Hospitalizat	cation re tion"				
AEOUT		Final Outcome 1=Resolved 2=Resolved w 3=Not resolved 4=Death*	ith Sequelae d (Skip questions 11	-			
			Date/			1)	
	11b.	Final Outcome	Time AEENDT	Chh:mm, 24-h	our clock)		

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Women's Treatment For Trauma And Substance Use Disorders:

AE	PAGE 2 OF 2

CTP - Site ID	Participant ID	A Data			,					
	USUBJID	Assessment Date:	m	<u> </u>	/ <del>_</del>	d '	A y	,EDI y	LC_ y	<del>y</del>

12. Signature:(MD, PhD, or PI) Date signed:// <u>AESIGDT</u> (mm/dd/)	12. Signature:	(MD, PhD, or PI)	Date signed:	, , AESIGDT	(mm/dd/yyyy
---	----------------	------------------	--------------	-------------	-------------

<sup>\*</sup> All Serious Adverse Events (SAE) must have a complete AE CRF, SAE Form, SAE Summary Report. Initial and date once these steps are completed.

Report AE/SAEs in accordance with the study protocol and local IRB requirements

SAEs must be reported within 24 hours (see SOM)

DOMAIN: LB

## URINE DRUG SCREEN (UDS)

### LBCAT=DRUG SCREEN STUDYID

PAGE 1 OF 1

OKINE DIGO OCK	(555)				INGLIGIT	
NIDA-CTN-0015 Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial					Seq. Num.:	
NODE:	NODE: USUBJID Baseline Wk1v1 Wk1v2 V					
CTP-SITE ID:	STUDY Visit: Wk3v1 Wk3v2 Wk4v1 Wk4v2 (circle one) Wk6v1 Wk6v2 1-Wk FUP 3-Mont					
PARTICIPANT ID:		_	EPO		VICITALIM	
Assessment Date: / / (mm / dd / yyyy)						
FORM COMPLETION STATUS  1-CRF Administered 4-Not enough time to Adi 5-No Participant Contact 3-Staff Member did not Administer 6-Other						
1. Was a Urine Drug Screen Performed? (0=No, 1=Yes, 7=Lost Sample, 9=Unknown)  # 0 or 9, the questionnaire is completed. If 7, answer only questions 1 and 2 of this CRF. QNAM=LBVISDTC  QLABEL=URINE COLLECTION VISIT DATE    IDVAR = LBSEQ   IDVAR =						
0 = No 1 = Yes	0 = No					
4. Was this urine	Was this urine collection supervised?					
0 = No 1 = Yes 9 = Uni	QLABE	= LBSUPER EL = URINE COLLE = LBSEO	ECTION SUF	PERVISED		

	le the number representing the result e screen for each substance below.)	Negative	Positive	Unclear or Equivocal	Results Not Valid	Not Assessed
5.	Amphetamines LBTEST	0	1 LBC	ORRES	3	8
6.	Barbiturates	0	1	2	3	8
7.	Benzodiazepines	0	1	2	3	8
8.	Methadone	0	1	2	3	8
9.	Tricyclic Antidepressants	0	1	2	3	8
10.	Cocaine metabolites	0	1	2	3	8
11.	Methamphetamines	0	1	2	3	8
12.	Opiates/Morphine	0	1	2	3	8
13.	Phencyclidine (PCP)	0	1	2	3	8
14.	Cannabinoids (THC)	0	1	2	3	8

DOMAIN: LB PAGE 1 OF 1 LBCAT=SALIVA TEST STUDYID SALIVA TEST (ST) Women's Treatment For Trauma And Substance Use Disorders: NIDA-CTN-0015 Seq. Num.: A Randomized Clinical Trial Baseline Wk1v1 Wk1v2 Wk2v1 Wk2v2 NODE: Wk3v1 Wk3v2 Wk4v1 Wk4v2 Wk5v1 Wk5v2 STUDY Visit: CTP-SITE ID: (circle one) Wk6v1 Wk6v2 1-Wk FUP 3-Month FUP 6-Month FUP **USUBJID** VISITNUM 12-Month FUP **EPOCH** PARTICIPANT ID: **LBDTC** / STAFF ID: Assessment Date: (mm / dd / yyyy) 1-CRF Administered 4-Not enough time to Administer FORM COMPLETION STATUS 2-Participant refused 5-No Participant Contact 3-Staff Member did not Administer 6=Other (Research Assistant/Independent Assessor Completed) Was a Saliva Test performed? 0=No LBTEST 1=Yes 7=Lost Sample 9=Unknown (if 0 or 9, skip to Q4 and enter a comment.) 2. Date Saliva Test was performed: \_\_\_/\_\_/\_\_(mne/dd/yyyy) Saliva Test result: \_\_\_\_ (If sample was lost, skip question 3.) QNAM=STVISDTC 0=Negative LBTEST 1=Positive **LBORRES** QLABEL=SALIVA TEST DATE 9=Unknown

COMMENTS:		
	DOMAIN: CO	
	COREF=SALIVA TEST	
	COVAL	
	RDOMAIN=LB	
	IDVAR= VISITNUM	

Modified: 10/27/2003

IDVAR = LBSEQ

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4.

CLINICAL GLOBAL IMPRESSION (CGI) QSCAT

**STUDYID** 

PAGE 1 OF 1

NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial				Seq. Num.:	
NODE:		Baseline 1			1-Wk FUP	
CTP-SITE ID:		STUDY Visit: (circle one) 3-Month E		h FUP 6-Month FU	JP 12-Month FUP	
PARTICIPANT ID:	USUBJID			EPOCH	VISITNUM	
Assessment Date:	// QSDTC(mm / dd / yyyy)			STAFF ID:	QSEVAL	
FORM COMPLE	TION STATUS 2-	1=CRF Administered 4=Not enough time to A 2=Participant refused 5=No Participant Conta 3=Staff Member did not Administer 6=Other				

(Independent Assessor Completed)

Problem Area	Current Severity (Use codes below)
QSTEST 1. Global	QSORRES
2. PTSD	
3. Depression	
4. Alcohol Abuse/Dependence	
5. Cocaine Abuse/Dependence	
6. Heroin Abuse/Dependence	
7. Marijuana Abuse/Dependence	
8. Sedatives Abuse/Dependence	
Other Drugs: Abuse/Dependence     specify:	

#### SEVERITY CODES

- 1 = no pathology
- 2 = minimal pathology or sub threshold symptoms

- 3 = mild pathology 4 = moderate pathology 5 = moderately severe pathology
- 6 = severe pathology
- 7 = extreme pathology
- 8 = not assessed
- 9 = not applicable

DOMAIN: SC, DM, DS STUDYID RANDOMIZATION (RAN) PAGE 1 OF 1 Women's Treatment For Trauma And Substance Use Disorders: NIDA-CTN-0015 Seq. Num.: A Randomized Clinical Trial NODE: Baseline STUDY Visit: CTP-SITE ID: (circle one) **EPOCH** VISITNUM **USUBJID** PARTICIPANT ID: SCDTC/DSDTC/mm / dd / yyyy) STAFF ID: \_\_/\_ Assessment Date: 4-Not enough time to Administer -CRF Administered 2-Participant refused 3-Staff Member did not Administer 5=No Participant Contact FORM COMPLETION STATUS 6-Other (Research Assistant Completed)
SC.SCORRES SC.SCTEST YES NO 1 0 A. Does the Participant continue to meet eligibility criteria? 1 0 B. Is the Participant currently taking psychotropic medication? SC.SCORRES SC.SCTEST YES NO RANDOMIZATION 1 0 Was Participant randomized? (If no, skip to question 3a. If yes, continue to question 1a) \_\_\_\_\_/ \_\_\_ DM.RFSTDTC Date of Randomization (mm / dd / yyyy) 1.a. \_\_\_\_ Randomization number. 2.a. \_\_\_ Randomization Group Assignment? 2.b. 1 - Experimental (Seeking Safety) DM.ARM 2 - Control (Women's Health Education) DS.DSOCCUR DS.DSTERM YES NO If not randomized, reasons not randomized: 1 0 3.a. Failed to return to clinic DS.DSCAT=DISPOSITION EVENT 0 Declined study participation (Specify in comments below) 0 Moved from area (current or pending) 0 3.d. Incarceration (current or pending) 0 3 e Death

3. f. Failed to meet inclusion criteria or met exclusion criteria

COREF DISPOSITION EVENT

Other (if other, then specify in 3h)

Variables COVAL RDOMAIN=DS IDVAR=VISITNUM

Specify Other:

Composition: CO

0

3.g.

3.h.

4.

**STUDYID DOMAIN: TU** 

THERAPY SESSION ATTENDANCE (TSA)

TUCAT=THERAPY SESSION ATTENDANCE

PAGE 1 OF 1

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		12711102				
NIDA-CTN-0015	Wome	en's Treatm	nent For Trauma A Randomized		ce Use Disorders:	Seq. Num.:
NODE:				EPOCH	Wk1v1 Wk1v2 Wk2v	v1 Wk2v2
CTP-SITE ID:			STUDY Visit:	VISITNUM	Wk3v1 Wk3v2 Wk4v	v1 Wk4v2
PARTICIPANT ID:	USU	JBJID		VISHNUM	Wk5v1 Wk5v2 Wk6v	r1 Wk6v2
Assessment Date:		//	TUDTC (	mm / dd / yyyy)	STAFF ID:	TUEVAL
FORM COMPLET	ION ST	TATUS 2	1=CRF Administered 2=Participant refused 3=Staff Member did no		4-Not enough time to Ad 5-No Participant Contact 6-Other	
(Research Assistant Co	omplete	ed)				
		Session	Attendance	TUTEST/T	UTESTCD	
TUORRES	1.	1=Expe 2=Cont	erimental (Seeking S trol (Women's Healt	th Education)		
	2a.	Session to	topic number (see	ə box at bottom f	for details)	
	2b.	Session of	cycle number (No	or the same as 2a	a)	
	3.	1=Yes	articipant person (skip to question 9) (continue)	nally attend th	his therapy session?	,
		Missed S	Session	TUTEST/	TUTESTCD	
TUORRES	4.	Did the pa 1=Yes 0=No		unicate with t	the research staff ab	oout this absence?
	5.	Date of la	st contact with p	participant: _	//	(mm/dd/yyyy)
	6.				sed sessions since the articipant. (Including the	
	7.	1=Yes	articipant view a (continue) (skip to question 9)	taped versio	on of the session?	
	8.	Enter the	date when the r	missed session	on videotape was vie	ewed:
		/_	_/	(mm/dd/yyyy)		
		Next Sch	neduled Session	n		
	9.	Date:	_!!	(mm/dd/)	VYYY)	
			Soccion '	Tonice		

Session Topics							
Seeking Safety sessions:		Women's Health Educ	ation sessions:				
1=Safety	7=Red and Green Flags	1-Body Systems	7=Pregnancy				
2-PTSD: Taking Back Your Power	8=Honesty	2-Female Anatomy	8-STDs				
3-Detaching from Emotional Pain	9-Integrating the Split Self	3=Breast Care	9=Nutrition				
4-When Substances Control You	10-Creating Meaning	4-Infections	10=High Blood Pressure				
5-Taking Good Care of Yourself	11-Setting Boundaries in Relationships	5=HIV/AIDS	11=Dlabetes				
6-Compassion	12=Healing Form Anger	6-Contraception	12=Menopause				

**STUDYID DOMAIN: TU** 

Non-Study Medical Services (NSMS) TUCAT=ACTIVE STUDY PHASE PAGE 1 OF 1

		·				_		
NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial						Seq. Num.:	
NODE:			Wk1v1	Wk1v2	Wk2v1	Wk2v2	2 Wk3v1	Wk3v2
CTP-SITE ID:		STUDY Visit: (circle one)	Wk4v1	Wk4v2	Wk5v1 Wk5v		Wk6v1	Wk6v2
PARTICIPANT ID:	USUBJID		Ef	POCH	OCH 1-Wk FUP		VISIT	NUM
Assessment Date:	// TUDTC(mm / dd / yyyy)				D:	TUEVA	<u>L</u>	
FORM COMPLE	1=CRF Administered 2=Participant refused 3=Staff Member did no	4-Not enough time to Administer 5-No Participant Contact 6-Other						

(Research Assistant Completed)

TUTEST/ TUTESTCD
When did the participant last complete this form?

- 1	/ TUORRES(mm/dd/yyyy	0
	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	r

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We'd like you to answer these questions for the medical services you've received including those that are part of this outpatient program (but excluding those associated with this study).

parcor	4115 0	uquati	ent program (but excluding those associated with this study).
Yes	No		Since your last assessment, have you TUTEST/TUTESTCD
1 TUOR	0 RES	1a.	Seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for drug, psychological, or emotional problems? (If no or not answered, then skip to question 2a, below)
10010	IKLO	1b.	TUORRES (If YES), how many times did you see a psychiatrist or psychologist?
		1c.	(If YES), how many times did you see a counselor or social worker?
1	0	2a.	Visited a medical office, not including your therapist? (Include all visits to a physician, nurse, or nurse practitioner, or physician's assistant) (If no or not answered, then skip to question 3a, below)
		2b.	(If YES), how many visits to a medical office have you had?
		2c.	(If YES), how many of these visits did you see a doctor?
1	0	За.	Been admitted into a residential program to detoxify or for other services? (If no or not answered, then skip to question 4a, below)
		3b.	(If YES), how many admissions?
		3c.	(If YES), how many nights for all stays?
1	0	4a.	Been admitted into a hospital to detoxify? (If no or not answered, then skip to question 5a, below)
		4b.	(If YES), how many admissions?
		4c.	(If YES), how many nights for all stays?
1	0	5a.	Been admitted to the hospital for any other reason? (If no or not answered, then skip to question 6a, below)
		5b.	(If YES), how many times were you admitted?
		5c.	(If at least once), how many nights for all stays?
1	0	ва.	Visited an emergency room and not been admitted to the hospital? (If no or not answered, then skip to question 7a, below)
		6b.	(If YES), how many times did you visit the emergency room?
1	0	7a.	Attended any 12-step or self – help meetings? (if no or not answered, then end interview)
		7b.	(If YES), how many times did you attend 12-step or self – help meetings?

QSCAT STUDYID

HELPING ALLIANCE QUESTIONNAIRE - COUNSELOR FORM (HAQC)

DOMAIN: QS PAGE 1 OF 1

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	(					
NIDA-CTN-0015	Women's Treat	rs: Seq. Num.:				
NODE:						
CTP-SITE ID:		STUDY Visit: (circle one)	Wk2v1	Wk6v1		
PARTICIPANT ID:	USUBJID		EPOCH	VISITNUM		
Assessment Date:	/	/ QSDTC(m	m / dd / yyyy) STAFF II	D:QSEVAL		
FORM COMPLE	ETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not	5−No Participant	4-Not enough time to Administer 5-No Participant Contact 6-Other		

(Counselor Completed)

Instructions: These are ways that a person may feel or behave in relation to another person – their client. Consider carefully your relationship with your client, and then mark each statement according to how strongly you agree or disagree. Please mark every one.

			QSOR	RES			
#	QSTEST/QSTESTCD	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
1	The client feels she can depend upon me.	1	2	3	4	5	6
2	She feels I understand her.	1	2	3	4	5	6
3	She feels I want her to achieve her goals.	1	2	3	4	5	6
4	At times, the client distrusts my judgment.	1	2	3	4	5	6
5	The client feels she is working together with me in a joint effort.	1	2	3	4	5	6
6	I believe we have similar ideas about the nature of her problems.	1	2	3	4	5	6
7	The client generally respects my views about her.	1	2	3	4	5	6
8	The client believes the procedures used in her therapy are $\underline{\text{not}}$ well-suited to her needs.	1	2	3	4	5	6
9	The client likes me as a person.	1	2	3	4	5	6
10	In most sessions, we find a way to work on her problems together.	1	2	3	4	5	6
11	The client believes I relate to her in ways that <u>slow up</u> the progress of the therapy.	1	2	3	4	5	6
12	The client believes a good relationship has formed between us.	1	2	3	4	5	6
13	The client believes I am experienced in helping people.	1	2	3	4	5	6
14	I want very much for the client to work out her problems.	1	2	3	4	5	6
15	The client and I have meaningful exchanges.	1	2	3	4	5	6
16	The client and I sometimes have unprofitable exchanges.	1	2	3	4	5	6
17	From time to time, we both talk about the same important events in her past.	1	2	3	4	5	6
18	The client believes I like her as a person.	1	2	3	4	5	6
19	At times, the client sees me as distant.	1	2	3	4	5	6

OSCAT

STUDYID

HELPING ALLIANCE QUESTIONNAIRE - PARTICIPANT (HAQP)

PAGE 1 OF 1

DOMAIN: QS

	(0_011011111		/	/			
NIDA-CTN-0015	Women's Trea	Seq. Num.:					
NODE:							
CTP-SITE ID:		STUDY Visit: (circle one)	v	Wk2v1 Wk2v2 Wk3v1 Wk3v2 Wk6v1 Wk6v2 1-Wk FUP			
PARTICIPANT ID:	USUBJID		E	VISITNUM			
Assessment Date:	/	_/ <u>QSDTC</u>	nm / dd / yyyy)	STAFF ID:	QSEVAL		
FORM COMPLE	ETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did no	2=Participant refused		4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Research Assistant Completed)

A. Counselor Id: \_\_\_\_QSTEST/QSTESTCD QSORRES

Instructions: These are ways that a person may feel or behave in relation to another person – their counselor. Consider carefully your relationship with your counselor, and then mark each statement according to how strongly you agree or disagree. Please mark every one.

				QSO	RRES		
#	QSTEST/QSTESTCD	Strongly Disagree	Disagree	Slighthy Disagree	Slightly Agree	Agree	Strongly Agree
1	I feel I can depend upon the counselor.	1	2	3	4	5	6
2	I feel the counselor understands me.	1	2	3	4	5	6
3	I feel the counselor wants me to achieve my goals.	1	2	3	4	5	6
4	At times, I distrust the counselor's judgment.	1	2	3	4	5	6
5	I feel I am working together with the counselor in a joint effort.	1	2	3	4	5	6
6	I believe we have similar ideas about the nature of my problems.	1	2	3	4	5	6
7	I generally respect the counselor's views about me.	1	2	3	4	5	6
8	The procedures used in my therapy are <u>not</u> well-suited to my needs.	1	2	3	4	5	6
9	I like the counselor as a person.	1	2	3	4	5	6
10	In most sessions, the counselor and I find a way to work on my problems together.	1	2	3	4	5	6
11	The counselor relates to me in ways that <u>slow up</u> the progress of the therapy.	1	2	3	4	5	6
12	A good relationship has formed with my counselor.	1	2	3	4	5	6
13	The counselor appears to be experienced in helping people.	1	2	3	4	5	6
14	I want very much to work out my problems.	1	2	3	4	5	6
15	The counselor and I have meaningful exchanges.	1	2	3	4	5	6
16	The counselor and I sometimes have $\underline{un}profitable$ exchanges.	1	2	3	4	5	6
17	From time to time, we both talk about the same important events in my past.	1	2	3	4	5	6
18	I believe the counselor likes me as a person.	1	2	3	4	5	6
19	At times, the counselor seems distant.	1	2	3	4	5	6

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SEEKING SAFETY FEEDBACK QUESTIONNAIRE (SSQ) STUDYID

PAGE 1 OF 1

	16/	-4		and Carlendan	ce Use Disorders:	
NIDA-CTN-0015	women's rre		nt For Trauma A A Randomized (		ce use Disorders:	Seq. Num.:
			A Randonnized (	Jimicai Iriai		ocq. Ham
NODE:						
CTP-SITE ID:			STUDY Visit: (circle one)		Wk6v2 1-Wk F	:UP
PARTICIPANT ID:	USUBJID				EPOCH	VISITNUM
Assessment Date: / /		/ QSDTC (mm / dd / yyyy)		m / dd / yyyy)	STAFF ID:	QSEVAL
FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Research Assistant Completed)

Your honest feedback about the Seeking Safety treatment would be greatly appreciated, so that possible future revisions of it can be as helpful as possible.

QSTEST/QSTESTCD

**QSORRES** 

	How helpful is the <u>treatment</u> ?	Greatly harmful	Somewhat harmful	A little harmful	Neutral	A little helpful	Somewhat helpful	Greathy helpful	N/A (missed session)
1	How helpful is the treatment overall?	-3	-2	-1	0	1	2	3	-9
2	How helpful is the treatment for PTSD and substance abuse?	-3	-2	-1	0	1	2	3	-9
3	How helpful is the treatment for PTSD alone?	-3	-2	-1	0	1	2	3	-9
4	How helpful is the treatment for substance abuse alone?	-3	-2	-1	0	1	2	3	-9
	How helpful are each of the topics?								
5	Safety	-3	-2	-1	0	1	2	3	-9
6	PTSD: Taking Back Your Power	-3	-2	-1	0	1	2	3	-9
7	Detaching from Emotional Pain (Grounding)	-3	-2	-1	0	1	2	3	-9
8	When Substances Control You	-3	-2	-1	0	1	2	3	-9
9	Taking Good Care of Yourself	-3	-2	-1	0	1	2	3	-9
10	Compassion	-3	-2	-1	0	1	2	3	-9
11	Red and Green Flags	-3	-2	-1	0	1	2	3	-9
12	Honesty	-3	-2	-1	0	1	2	3	-9
13	Integrating the Split Self	-3	-2	-1	0	1	2	3	-9
14	Creating Meaning	-3	-2	-1	0	1	2	3	-9
15	Setting Boundaries in Relationships	-3	-2	-1	0	1	2	3	-9
16	Healing from Anger	-3	-2	-1	0	1	2	3	-9

#### QSCAT STUDYID

**DOMAIN: QS** 

WOMEN'S HEALTH EDUCATION FEEDBACK QUESTIONNAIRE (WHQ)

$P\Delta$	GE	1	ΩE	*

NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial					Seq. Num.:
NODE:						
CTP-SITE ID:			STUDY Visit: (circle one)			1-Wk FUP
PARTICIPANT ID:	USUBJID				EPOCH	VISITNUM
Assessment Date:	/	_ /	QSDTC (m	ım / dd / yyyy)	STAFF ID: _	QSEVAL
FORM COMPLETION STATUS			1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4-Not enough time to A 5-No Participant Conta 6-Other	

(Research Assistant Completed)

Your honest feedback about the Women's Health Group would be greatly appreciated, so that possible future revisions of it can be as helpful as possible.

				(	SOR	RES			
	QSTEST/QSTESTCD  How helpful is the group?	Greatly harmful	Somewhat hamnful	A little harmful	Neutral	A little helpful	Somewhat helpful	Greatly helpful	N/A (Missed Session)
1	How helpful is the group overall?	-3	-2	-1	0	1	2	3	-9
	How helpful are each of the topics?								
2	Basic Human Biology-What Are My Body's Systems?	-3	-2	-1	0	1	2	3	-9
3	The Female Reproductive Systems	-3	-2	-1	0	1	2	3	-9
4	Women's health issues (part one): Breast Care	-3	-2	-1	0	1	2	3	-9
5	Women's health issues (part two): Vaginitis	-3	-2	-1	0	1	2	3	-9
6	Introduction to HIV/AIDS	-3	-2	-1	0	1	2	3	-9
7	Contraception and Safer Sex	-3	-2	-1	0	1	2	3	-9
8	Pregnancy and Childbirth	-3	-2	-1	0	1	2	3	-9
9	Sexually Transmitted Diseases	-3	-2	-1	0	1	2	3	-9
10	Nutrition	-3	-2	-1	0	1	2	3	-9
11	High Blood Pressure	-3	-2	-1	0	1	2	3	-9
12	Diabetes	-3	-2	-1	0	1	2	3	-9
13	Menopause	ကု	-2	-1	0	1	2	3	-9

### **STUDYID**

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STODY TERMINATION - TREATMENT (STT) DOMAIN: DS PAGE							
NIDA-CTN-0015	Women's Trea	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial					
NODE:							
CTP-SITE ID:		STUDY Visit: (circle one)	EPOC				
PARTICIPANT ID:	USUBJID		VISIT	NUM			
Assessment Date:	:/	_ / _DSDTC(m	m / dd / yyyy)	STAFF ID:			
FORM COMPLE	ETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not	Administer	4-Not enough time to Adm 5-No Participant Contact 6-Other	ninister		

(Research Assistant Co	DSCAT= TREATMENT TERMINATION
DSTERM/DSDECOD.	Date of Treatment Phase completion or early termination:// _DSSTDTC// _DSSTDTC
2.	Number of group therapy sessions attended by the Participant.
YES NO UNK QNA	M = DSNMSESS, QLABEL = NUMBER OF SESSIONS ATTENDED, IDVAR = DSSEC
1 0 -9 3.	Did the Participant terminate treatment before the end of the Treatment Phase (early
DSTERM/DSDECOD	termination)? (If No, then skip to question 10. If Yes or Unk, then complete questions 4a through 10.)
	REASON FOR EARLY TERMINATION
YES NO UNK	Complete this section if answered "Yes" or "Unk" in question 3.
DSTERM/DSDECOD	Was the Participant discharged from the CTP for administrative reasons? (i.e., active disruption of CTP procedures, non-compliance with CTP rules, etc.) (If Yes, answer 4b. If No or UNK, skip to 5a.)  DSSTDTC
4b.	If Yes, date of CTP discharge:// (mm/dd/yyyy)
1 0 -9 5a.	Was the Participant discontinued from the study for administrative reasons? (i.e., active disruption of counseling, protocol non-compliance, etc.)
DSTERM/DSDECOD	(If Yes, answer 5b and 5c. If No or ÜNK, skip to 6a.)  DSSTDTC
5b.	If Yes, date of study discontinuance:// (mm/dd/yyyy)
1 0 -9 5c. DSTERM/DSDECOD	Was the Participant discontinued for missing 4 consecutive scheduled visits without contact with the RA/IA?
1 0 -9 6a. DSTERM/DSDECOD	Was the participant discontinued from the study for clinical reasons? (I.e., concurrent illness, serious adverse events, etc.) (If Yes, answer 6b. If No or UNK, skip to 7.)
6b.	If Yes, date of study discontinuance: / / DSSTDTC (mm/dd/yyyy)
1 0 -9 7.	Was the Participant discontinued at her request?
DSTERM/DSDECOD 1 -9 8.	Did the Participant discontinue the protocol for another reason? (If Yes, then specify in question 8.)
9.	If any question above was answered Yes, then provide details:
	DOMAIN: CO COREF=TREATMENT TERMINATION Variables COVAL
	RDOMAIN=DS CONTINUATION =VISITNUM
1 0 -9 10.	

QNAM = DSCONTIN, QLABEL = CONTINUE INTO FOLLOW-UP PHASE?, IDVAR = DSSEQ Modified: 8/6/2003

STUDYID DOMAIN: QS ADDICTION SEVERITY INDEX-LITE FOLLOW-UP (ASF) =QSCAT PAGE 1 OF 14 Women's Treatment For Trauma And Substance Use Disorders: NIDA-CTN-0015 Seq. Num.: \_\_ \_ A Randomized Clinical Trial NODE: **EPOCH** VISITNUM STUDY Visit: CTP-SITE ID: 1-Wk FUP 3-Month FUP 6-Month FUP 12-Month FUP (circle one) USUBJID PARTICIPANT ID: **QSDTC QSEVAL** STAFF ID: 1 (mm / dd / yyyy) Assessment Date: 1-CRF Administered 4-Not enough time to Administer 5-No Participant Contact 2-Participant refused FORM COMPLETION STATUS 3-Staff Member did not Administer 6=Other (Independent Assessor Completed) Participant Date of Birth (mm/dd/yyyy): Composite Scores (for site use only): Medical: Legal: Employment: Family: Psychiatric: Drug: Alcohol: KFY: Introducing the ASI Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Patient Rating Family/Social, and Psychological. All clients receive this same standard interview. All information Scale gathered is confidential. There are two time periods we will discuss: 0 = Not at all The past 30 days
 Since your last ASI 1 = Slightly 2 = Moderately Patient Rating Scale: Patient input is important. For each area, I will ask you to use this scale to let me 3 = Considerably know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed. 4 = Extremely Please refer to the Patient Rating Scale in the adjacent key. If you are uncomfortable giving an answer, then don't answer. Please do not give inaccurate information! Interviewer Instructions Leave no blanks. Make plenty of Comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems). Throughout the ASI, when noted: X = Question not answered. N = Question not applicable. 4.Terminate interview if client misrepresents two or more sections. When noting comments, please write the question number. HALF TIME RULE: If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.

- CONFIDENCE RATINGS: ⇒ Last two items in each section.
  - ⇒ Do not over interpret.
  - ⇒ Denial does not warrant misrepresentation.
  - ⇒ Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

ΔSF PAGE 2 OF 14

CTP - Site ID	Participant ID	Assessment Date:		/		_	/			
			m	m	d	d	у	У	у	у

#### Hollingshead Categories

- Higher Executive, Major Professionals, Owner of Large Business 1 =
- 2 = Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)
- 3 = Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
- 4 = Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
- 5 = Skilled Manual—usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist. mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
- 6 = Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
- 7 = Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include Unemployed.
- 8 = Homemaker
- 9 = Student/No Occupation/Disabled

#### List of Commonly Used Drugs

Alcohol: Beer, wine, liquor

Methadone: Dolophine, LAAM

Opiates: Pain killers = Morphine, Diluaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4,

Syrups = Robitussin, Fentanyl

Barbiturates: Nembutal, Seconal, Tuinol, Ámytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol

Sed/Hyp/Tranq: Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown,

Other = ChloralHydrate (Noctex), Quaaludes

Cocaine Crystal, Free-Base Cocaine or "Crack, and "Rock Cocaine" Cocaine:

Amphetamines: Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal

Cannabis: Marijuana, Hashish

Hallucinogens: LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy

Inhalants: Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants.

Ulcer Meds = Zantac, Tagamet

Asthma Meds = Ventoline Inhaler, Theodur Other Meds = Antipsychotics, Lithium

#### Alcohol/Drug Section Instructions

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol /drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

- 30 day questions only require the number of days used.
- ⇒ Lifetime use is asked to determine extended periods of use.
- ⇒ Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
- ⇒ Alcohol to intoxication does not necessarily mean "drunk", use the words "felt the effects", "got a buzz", "high", etc. instead of intoxication. As a rule of thumb, 5+ drinks in one setting, or within a brief period of time defines "intoxication".

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- ⇒ How to ask these questions:
  - → "How many days in the past 30 have you used....?"
  - → "How many years in your life have you regularly used....?"

ASF

DOMAIN: QS
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CTP - Site ID	Participant ID	Assessment Date: / QSDTC	
	<u>USUBJID</u>	m m d d y y y y	

### GENERAL INFORMATION =QSSCAT

Q <u>SOR</u> RES	G9.	QSTEST Contact code: 1-In person 2-Telephone (Intake ASI must be In person) 3-Mail X=Not Answered	Comments:
	G12.	Special: 1-Patient terminated 2-Patient refused 3-Patient unable to respond N=Not Applicable	
_	G19.	QSEVLINT=-P30D  Have you been in a controlled environment in the past 30 days? A place, theoretically, without access to drugs/alcohol.  1=No	
	G20.	How many days? "NN" if question G19 is "No". Refers to total number of days detained in the past 30 days. (XX=Not Answered)	
		QSEVLINT=-P30D QSORRESU=DAY	

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DOMAIN: QS

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CTP - Site ID	Participant ID	Accordant Bates / CODTO
	USUBJID	m m d d y y y y

### MEDICAL STATUS =QSSCAT

		QSTEST	
QSORRES	M1.	Since your last ASI, how many times have you been hospitalized for medical problems?	Comments:
		Include O.D.'s, D.T.'s. Exclude detox, alcohol/drug, and psychiatric treatment and childbirth (if no complications). Enter the number of overnight hospitalizations for medical problems. (XX=Not Answered)	
0=No. 1=Yes	M4.	Are you taking any prescribed medication on a regular basis for a physical problem?	
		Medication prescribed by a MD for medical conditions; <u>not psychiatric medicines</u> , include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems. (X= Not Answered)	
		If "Yes," specify:	
0=No, 1=Yes	M5.	Do you receive a pension for a physical disability? (X= Not Answered)	
		include Workers' compensation, exclude psychlatric disability.	
		If "Yes," specify:	
——	M6.	How many days have you experienced medical problems in the past 30 days? QSORRESU=DAY QSEVLINT=-P	30D
		Do not include aliments directly caused by drugs/alcohol. Include flu, colds, etc. Include serious aliments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.). (X=Not Answered)	
		Questions M7 & M8, please ask the patient to use the ent Rating scale.	
	M7.	How troubled or bothered have you been by these medical problems in the past 30 days? QSEVLINT=-P30D Restrict response to problem days of Question M6. (X=Not Answered)	
	M8.	How important to you <u>now</u> is treatment for these medical problems?  Refers to the need for <u>new or additional</u> medical treatment by the patient. (X=Not Answered)	
	CON	FIDENCE RATINGS THIS DATA NOT ENTERED	
	Is the	above information significantly distorted by:	
0 <del>-No, 1-Ye</del> s	M10.	Patient's misrepresentation?	
0 <del>-</del> No, 1-Yes	M11.	Patient's inability to understand?	

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DOMAIN: QS

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CTP - Site ID	Participant ID	Assessment Date: / /	QSDTC
	USUBJID	m m d d	-y y y y

### EMPLOYMENT/SUPPORT STATUS = QSSCAT

		THOUSE CHAICO	
a. Yrs. / b. Mos.	E1.	Education completed since your last ASI?QSTEST  GED = 12 years. Include formal education only. (XXXXX=Not Answered)	Comments:
QSORRES	E2.	Training or technical education completed since your last ASI:	
Mos.		Formal/organized training only. For military training, only include training that can be used in civilian life (i.e., electronics or computers). (XX=Not Answered)	
0=No, 1=Yes	E4.	Do you have a valid driver's license? Valid license; not suspended/revoked. (X=Not Answered)	
0=No, 1=Yes	E5.	Do you have an automobile available? ( <u>if answer to E4 is "No", then E5 must be "No"</u> )  Does not require ownership, only requires availability on a regular basis.  (X=Not Answered)	
	-7	,	
	E/.	Usual (or last) occupation since your last ASI?	
		(specify:) (Use Hollingshead Categories Reference Sheet) (X=Not Answered)	
	Ε0	Does someone contribute the majority of your support?	
0=No, 1=Yes	Eð.	Is patient receiving any regular support (i.e., cash, food, housing) from	
		family/triend? Include spouse's contribution; exclude support by an Institution. (X=Not Answered, N=Not Applicable)	
——	E11	. How many days were you paid for working in the past 30 days?	
		include "under the table" work, paid sick days, and vacation. (XX=Not Answered)  QSORRESU=DAY QSEVLINT=-P30D	
Max=\$99999		questions E12-E17: How much money did you receive the following sources in the past 30 days?	
\$		. Employment? (Net or "take home" pay, Indude any under the lable" money.) (XXXXX=Not Answered)	
\$	E13	. Unemployment Compensation? (XXXXX=Not Answered)	
\$	E14	<ul> <li>Welfare? (Include food stamps, transportation money provided by an agency to go to and from treatment.) (XXXXX=Not Answered)</li> </ul>	
\$	E15	<ul> <li>Pensions, benefits or Social Security? (Include disability, pensions, retirement, veteran's benefits, SSI &amp; workers' compensation.) (XXXXX=Not Answered)</li> </ul>	
\$	E16	<ul> <li>Mate, family or friends? (Money for personal expenses, (i.e., clothing), Include unreliable sources of Income (e.g., gambling). Record <u>cash</u> payments only, Include windfalls (unexpected), money from loans, gambling, Inheritance, tax returns, etc.). (XXXX=Not Answered)</li> </ul>	QSORRESU=DOLLAR
\$	E17	. Illegal? (XXXXX=Not Answered)	
		Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. Do Not attempt to covert drugs exchanged to a dollar value.	
	E18	. How many people depend on you for the majority of their	_
Max = 99		food, shelter, etc.? Must be regularly depending on patient, do include allmony/child support, do not include the patient or self- supporting spouse, etc. (XX=Not Answered)	

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CTP-S	5.12.12					ant I				Ass	essme		_	1	_	_	/				_				
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QSORRES	E19.	QSTEST How many days have you experienced employment problems in the past 30 days? Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized. (XX=Wor Answered)QSEVLINT=-P30D QSORRESU=DAYS							Co	mn	ner	nts:							_						
	Ratin The par	or Questions E20 & E21, ask the patient to use the Patient sting scale.  e patient's ratings in Questions E20 & E21 refer to Question E19. Stress help inding or preparing for a job, not giving them a job.																							
	E20.	emple if the p	ow troubled or bothered have you been by these inployment problems in the past 30 days? The patent has been incarcerated or detained during the past 30 days, by cannot have employment problems. (X=Not Answered)																						
	E21.		How important to you <u>now</u> , is counseling for these employment problems? (X=Not Answered)																						
	CONFIDENCE RATINGS THIS DATA NOT ENTERED																								
	Is the	above	in	nfor	mati	on <u>s</u>	sign	ifica	antly	distort	ed	by:													
0=No, 1=Yes	E23.	Patie	nť	's n	nisre	pre:	sen	tatio	n?																
0=No, 1=Yes	E24.	Patie	nť	's ir	nabili	ity to	o ur	nder	stan	nd?															

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DOMAIN: QS

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CTP - Site ID	Participant ID	Assessment Date:	-	,		,	00	DT	
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### DRUG/ALCOHOL USE =QSSCAT

Route of Administration Types:

1 = Oral 2 = Nasai 3 = Smoking 4 = Non-IV injection 5 = IV injection

Note the <u>usual or most recent</u> route. For more than one route, choose the most severe. The routes are listed from least severe to most severe. If Past 30 Days is zero, route should be coded as "N" (XXSNot Answered)

	30 Days is zero, route should be coded as "N." (XX=Not Answered)  QSEVLINT=-P30D										
Sub	stance QSTEST	a. Past 30 Days		c. Route of Admin.	Comments:						
D1.	Alcohol (any use at all)	Q <u>SORRE</u> S									
D2.	Alcohol (to intoxication)										
D3.	Heroin										
D4.	Methadone/LAAM (prescribed)										
D4a.	Methadone/LAAM (illicit)				QNAM = QSRTADMN						
D5.	Other Opiates/Analgesics				QLABEL = ROUTE OF ADMIN.						
D6.	Barbiturates				IDVAR = QSSEQ						
D7.	Other Sedatives/Hypnotics/Tranquilizers										
D8.	Cocaine										
D9.	Amphetamines										
D10.	Cannabis										
D11.	Hallucinogens										
D12.	Inhalants										
D36.	Nicotine (tobacco products)										
D13.	More than 1 substance per day (including alcohol, excluding nicotine)										
QS	ORRES D14. According to the interview the major problem?  Interviewer should determine the	Comments:									

QSORRES	D14.	According to the interviewer, which substance(s) is/are the major problem? Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next—to the drug in questions 01-12, (code prescribed or Illicit methadone as "04"). "00" = no problem, "15" = alcohol & one or more drugs, "16" = more than one drug but no alcohol. Ask participant when not clear. (XX=Not Answered)	Comments:
	How m	any times since your last ASI have you:	
	D17.	Had Alcohol DT's? <u>Delidum Tremens</u> (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations, they usually require medical attention. (XX=Not Answered)	

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DOMAIN: QS

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QSORRES	Include deta	ny times since your last ASI have you been treated for: oxification, haifway houses, in/outpatient counseling, and AA or NA (If is within one month period). (XX=Not Answered)	Comments:
	D19. A	Alcohol abuse?	
	D20. D	rug abuse?	
	How man	ny of these were detox only?	
		Alcohol? If D19 = "00", then question D21 is "NN" (XX=Not inswered)	
		Orugs? If D20 = "00", then question D22 is "NN" (XX=Not inswered)	
Max		ch money would you say you spent during the past 30	
=\$99999		Only count actual money spent. What is the financial burden caused cohol? (XXXXX=Not Answered)	
\$	D23. A	Alcohol? QSEVLINT=-P30D QSORRESU=DOLLAR	
\$	D24. D	Orugs?	
	s	How many days have you been treated in an outpatient etting for alcohol or drugs in the past 30 days? (Include IA/NA) (XX=Not Answered)	
	Patient F	stions D28 - D31, please ask the patient to use the Rating scale.  It is rating the need for additional substance abuse treatment. (X=Not	
		ny days in the past 30 have you experienced:	
		cohol problems? QSEVLINT=-P30D QSORRESU=I	DAYS
	by these	ubled or bothered have you been in the past 30 days	
		QSEVLINT=-P30D cohol problems?	
	How imp	portant to you now is treatment for these:	
	D30. Ale	cohol problems?	
	How mai	ny days in the past 30 have you experienced:	
	Include: Cra	Orug problems? QSEVLINT=-P30D QSORRESU=[ aving, withdrawal symptoms, disturbing effects of use, or wanting to eling unable to. (XX=Nor Answered)	DAYS
		ubled or bothered have you been in the past 30 days	
	D29. Dr	QSEVLINT=-P30D rug problems?	
	How imp	portant to you now is treatment for these:	
	D31. Dr	rug problems?	
	CONFIDE	ENCE RATINGS THIS DATA NOT ENTERED	
	Is the abo	ove information significantly distorted by:	
	D34. P	Patient's misrepresentation?	
0=No, 1=Yes 0=No, 1=Yes		Patient's inability to understand?	
		·	

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CTP - Site ID	Participant ID	Assassment Date:			,		,	00	DT	
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## **LEGAL STATUS** =QSSCAT

QSORRES	•	OCTECT/OCTECTOD			
	L2.	QSTEST/QSTESTCD Are you on parole or probation?			Comments:
0=No, 1=Yes		Note duration and level in comments. (X=	Not A	nswered)	
How many fi	imes s	ince your last ASI have you beer	arr	ested and charged	ŀ
		Include total number of counts, not just or			
		ess they were charged as an adult. Include			
	L3. S	hoplifting/Vandalism	L10.	Assault	
	L4. P	arole/Probation Violations	L11.	Arson	
	L5. D	rug Charges	L12.	Rape	
	L6. F	orgery	L13.	Homicide/Manslaughter	
	L7. V	Veapons Offense	L14.	Prostitution	
	L8. B	lurglary/Larceny/B&E	L15.	Contempt of court	
	L9. R	lobbery	L16.	Other: (specify)	ļ
	L17.	How many of these charges result L3-L16= "00", then L17="NN". Do not from questions L18-L20 below. Convictio incarcerations, suspended sentences, and Answered)	e misdemeanor offenses Jude fines, probation,		
		many times since your last ASI h the following:	ave	you been charged	
	L18.	Disorderly conduct, vagrancy, pul Answered)	olic i	ntoxication? (XX=Not	
	L19.	Driving while intoxicated (DWI)? (X	X=No	t Answered)	
	L20.	Major driving violations? Moving violations: speeding, reckless driv Answered)	ing, n	o license, etc. (XX=Not	
Mos.	L21.	How many months were you inca ASI? (XX=Not Answered) QSOI If Incarcerated 2 weeks or more, round the of months incarcerated.	RRE	SU=MONTH	
0=No, 1=Yes	L24.	Are you presently awaiting charge Answered)	es, tr	ial, or sentence? (X=Not	

ASF

PAGE 10 OF 14 Participant ID CTP - Site ID Assessment Date: OSDTC **USUBJID** d d **QSTEST** QSEVLINT=-P30D QSORRESU=DAY **QSORRES** L25. What for? (Refers to L24.) Use code 03-16, 18-20. If more than one, Comments: choose most severe. Don't include civil cases, unless a criminal offense is involved. (XX=Not Answered, NN= Not Applicable) 03 - Shopliffing 12 - Rape 04 - Probation violation 13 - Homicide 14 - Prostitution 05 - Drug 06 - Forgery 15 - Contempt 07 - Weapons 16 - Other 18 - Disorderly conduct 08 - Burglary 09 - Robbery 19 - DWI 10 - Assault 20 - Major driving violation 11 - Arson L28. How many days in the past 30, were you detained or incarcerated? QSEVLINT=-P30D QSORRESU=DAY include being arrested and released on the same day. (XX=Not Answered) How many days in the past 30, have you engaged in L27. illegal activities for profit? QSEVLINT=-P30D QSORRESU=DAY Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross- checked with Question E17 under Employment/Family Support Section. (XX=Not Answered) For questions L28 & L29, ask the patient to use the Patient Rating scale. How serious do you feel your present legal problems are? L28. Exclude civil problems. (X=Not Answered) How important to you now is counseling or referral for L29. these legal problems? Patient is rating a need for additional referral to legal counsel for defense

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against criminal charges. (X=Not Answered)

Is the above information significantly distorted by:

CONFIDENCE RATINGS

L31. Patient's misrepresentation?

L32. Patient's inability to understand?

0=No. 1=Yes

0=No. 1=Yes

FAMILY/SOC	IAI RFI	ATIONSHIPS	=QSSCA
	IAL REL	.A I IONSHIFS	-0000/1

	_		
QSORRES	F1.	Marrital Status QSTEST  1 - Married 3 - Widowed 5 - Divorced 2 - Remarried 4 - Separated 6 - Never Married	Comments:
		Common-law marriage = "1." (Specify in comments) (X=Not Answered)	
0=No, 1=Indifferent, 2=Yes	F3.	Are you satisfied with this situation? (Refers to Question F1) Satisfied - generally liking the situation. (X=Not Answered)	
	F4.	Living arrangements (Since your last ASI):  1 - With sexual partner & children 6 - With friends  2 - With sexual partner alone 7 - Alone  3 - With children alone 8 - Controlled Environment  4 - With parents 9 - No stable arrangement  5 - With family	
		Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement. (X=Not Answered)	
0=No, 1=Indifferent, 2=Yes	F6.	Are you satisfied with these arrangements? Refers to response in Question F4. (X=Not Answered)	
	Do	you live with anyone who:	
0=No, 1=Yes	F7.	Has a current alcohol problem? (X=Not Answered)	
0=No, 1=Yes	F8.	Uses non-prescribed drugs? (X=Not Answered)	
1=Family, 2=Friends, 3=Alone	F9.	With whom do you spend most of your free time? If a girlfriend/boyfriend is considered as a family by patient, then they must refer to them as family throughout this section, not a friend. Family is not to be referred to as "friend." (X=Not Answered)	
0=No, 1=Indifferent, 2=Yes	F10	. Are you satisfied with spending your free time this way? (Refers to Question F9.) A satisfied response must indicate that the person generally likes the situation. (X=Not Answered)	
problems ge	etting	nificant periods in which you have experienced serious along with: "Serious problems" mean those that endangered the m" requires contact of some sort, either by telephone or in person.	
a. Past 30 <u>Days</u>	0=1	No, 1= Yes, (X= Not Answered, N= Not Applicable)	
		Mother QSEVLINT=-P30D Father	
	F20.	Brothers/Sisters	
	F21.	Sexual Partner/Spouse	
	F22.	Children	
	F23.	Other Significant Family (Specify)	
	F24.	Close Friends	
	F25.	Neighbors	
	F26.	Co-workers	

ASF

DOMAIN: QS
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731							AGE	120	ZE I	_
CTP - Site ID	Participant ID	Assessment Date:		,		,	QSE	тс	;	
	<u>USUBJID</u>		 m '		<u> </u>		у -	y -	y	

a. Past 30 <u>Days</u>	0= No, 1= Yes (X=Not Answered)	Comments:
	-P30D QSTEST Did anyone (Question F18 - F26) abuse you?	
SORRES	F28. Physically? (Caused you physical harm.)	
	F29. Sexually? (Forced sexual advances/acts.)	
	How many days in the past 30 have you had serious conflicts:	
	F30. With your family? (XX= Not Answered) QSEVLINT=-P30D C	SORRESU=DAY
	For Questions F32 and F34, ask the patient to use the Patient Rating scale.	
	How troubled or bothered have you been in the past 30 days by these:	
	F32. Family problems (X= Not Answered) QSEVLINT=-P30D	
	How important to you now is treatment or counseling for these:	
	F34. Family problems  Patient is rating his/her need for counseling for family problems, not whether the family would be willing to attend. (X= Not Answered)	
	How many days in the past 30 have you had serious conflicts:  QSEVLINT=-P30D  F31. With other people (excluding family)? (XX= Not Answered)	
	For Questions F33 and F35, ask the patient to use the Patient Rating scale.	
	How troubled or bothered have you been in the past 30 days by these:	
	QSEVLINT=-P30D	
	F33. Social problems (X= Not Answered)	
	How important to you now is treatment or counseling for these:	
	F35. Social problems Include patient's need to seek treatment for such social problems as ioneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if patient had no substance abuse. (X= Not Answered)	
	CONFIDENCE RATING THIS DATA NOT ENTERED	
	Is the above information significantly distorted by:	
0=No, 1=Yes	F37. Patient's misrepresentation?	
0=No, 1=Yes	F38. Patient's inability to understand?	

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ASF					PAGE 13 OF 14
CTP - Site ID	Participant ID	Assessment Date:	1		QSDTC
	USUBJID	Assessment Date:	-m m ′ d	'	' - <del>y y y y</del>

# PSYCHIATRIC STATUS=QSSCAT

ratuni/	ATRIC STATUS	
	COTTOT	Comments:
	OSTEST How many times since your last ASI have you been treated	
	for any psychological or emotional problems:	
	Do not include substance abuse, employment, or family counseling. Treatment	
	episode = a series of more or less continuous visits or treatment days, not the	
QSORRES	number of visits or treatment days. Enter diagnosis in comments if known.	
QUOTITE	P1. In a Hospital or inpatient setting? (XX= Not Answered)	
	P2. Outpatient/private patient? (XX= Not Answered)	
	P3. Do you receive a pension for a psychiatric disability? (X=Not	
0=No, 1=Yes	Answered)	
	Have you had a significant period of time (that was not a	
	direct result of alcohol/drug use) in which you have:	
a. Past 30		
a. rast so Days	0=No, 1=Yes, (X= Not Answered)	
Days	B4. Fire-design design design and the barries	
	P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	
QSEVLIN		
	P5. Experienced serious anxiety/tension-uptight, unreasonably	
	worried, inability to feel relaxed?	
	P8. Experienced hallucinations-saw things or heard voices that	
	other people did not see or hear?	
	P7. Experienced trouble understanding, concentrating, or	
	remembering?	
	•	
	See and the BO B40 and and the beautiful to the	
	For questions P8-P10, patient could have been under the influence of alcohol/drugs.	
	initialitie of alcoholidrags.	
	P8. Experienced trouble controlling violent behavior including	
	episodes of rage, or violence? (Patlent can be under the Influence of	
	alcohol/drugs.)	
	DO. Francisco de crisco de contra efecticido	
	P9. Experienced serious thoughts of suicide?	
	Patient seriously considered a plan for taking his/her life.	
	P10. Attempted suicide? (Include actual suicidal gestures or attempts.)	
	P11. Been prescribed medication for any psychological or	
	emotional problems? (Prescribed for the patient by MD. Record "Yes"	
	If a medication was prescribed even if the patient is not taking it.)	
	P12. How many days in the past 30 have you experienced these	
	psychological or emotional problems? (This refers to problems	
	noted in Questions P4-P10.) (XX= Not Answered)	
	QSEVLINT=-P30D QSORRESU=DAY	

P23. Patient's inability to understand?

0=No, 1=Yes

ASF PAGE 14 OF 14 Participant ID CTP - Site ID **QSDTC** Assessment Date: **USUBJID QSTEST** For Question P13 & P14, ask the patient to use the Patient Comments: Rating scale. **QSORRES** QSEVLINT=-P30D P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? (Patient should be rating the problem days from Question P12.) (X= Not Answered) P14. How important to you now is treatment for these psychological or emotional problems? (X= Not Answered) CONFIDENCE RATING THIS DATA NOT ENTERED Is the above information significantly distorted by: P22. Patient's misrepresentation? 0=No, 1=Yes

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ADDENDUM FOLLOW-UP (ADDF)	=QSCAT	DOMAIN: QS PAGE 1 OF
---------------------------	--------	----------------------

NIDA-CTN-0015	Women's Trea	Seq. Num.:			
NODE:		STUDYID	EPO		TNUM
CTP-SITE ID:		STUDY Visit: (circle one)			onth FUP Ionth FUP
PARTICIPANT ID:	USUBJID		١	-Month FOF 12-W	onth FOF
Assessment Date:	/	/ QSDTC	mm / dd / yyyy)	STAFF ID:	QSEVAL
FORM COMPLETION STATUS		1=CRF Administered 4=Not enough time to A 2=Participant refused 5=No Participant Conta 3=Staff Member did not Administer 6=Other			

(Independent Assessor Completed)

For questions 18 and 19, ask the Participant to consider only events that have happened since her last interview.

(Please note that the question numbering has been preserved from the Addendum CRF, and, therefore, the questions are not numbered sequentially.)

Yes	No	NA		QSTEST
1	0	-9	18a.	Since our last interview, has anyone used physical violence (such as being slapped,
(	QSORR	ES		pushed, hit or punched) or the threat of physical violence against you? (If yes, ask questions 18b-18f. If no or not answered, skip to question 19a.)
				If yes, how was this person related to you:
1	0	-9	18b.	Spouse?
1	0	-9	18c.	Other family member?
1	0	-9	18d.	Partner/significant other?
1	0	-9	18e.	Stranger?
1	0	-9	18f.	Did you receive medical treatment for any injuries as a result of physical violence against you?
Yes	No	NA		
1	0	-9	19a.	Since our last interview, has anyone used sexual violence (forcing you to do anything sexual) or the threat of sexual violence against you? (If yes, ask questions 19b-19f. If no or not answered, skip to question 22.)
				If yes, how was this person related to you:
1	0	-9	19b.	Spouse?
1	0	-9	19c.	Other family member?
1	0	-9	19d.	Partner/significant other?
1	0	-9	19e.	Stranger?
1	0	-9	19f.	Did you receive medical treatment for any injuries as a result of sexual violence against you?

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ADDF DOMAIN: QS PAGE 2 OF 2

CTP - Site ID	Participant ID USUBJID	Assessment Date:	m m	/	/ QSDTC
---------------	---------------------------	------------------	-----	---	---------

For guestions 22 through 26, ask the Participant to consider how she feels currently.

-		
QSORRES		Overall Health QSTEST
	22.	Please rate your current health status in general:  1 = Excellent 2 = Good 3 = Fair 4 = Poor 5 = Very poor -9 = Not answered
		Please tell me how much you agree or disagree with the following statements:
	23.	I am somewhat ill.  1 = Strongly agree  2 = Somewhat agree  3 = Neither agree nor disagree  4 = Somewhat disagree  5 = Strongly disagree  -9 = Not answered
	24.	I am as healthy as anybody I know.  1 = Strongly agree  2 = Somewhat agree  3 = Neither agree nor disagree  4 = Somewhat disagree  5 = Strongly disagree  -9 = Not answered
	25.	My health is excellent.  1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
	26.	I have been feeling bad lately.  1 = Strongly agree  2 = Somewhat agree  3 = Neither agree nor disagree  4 = Somewhat disagree  5 = Strongly disagree  -9 = Not answered

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**DOMAIN: TU** 

1 OF 1

TRAUMA SPECIFIC	TREATMENT (TST	) =TUCAT	STUDYID	PAGE

NIDA-CTN-0015	Women's Treatm	Seq. Num.:			
NODE:				EPOCH 1-Week FUP 3-M	VISITNUM onth FUP
CTP-SITE ID:		STUDY Visit: (circle one)			
PARTICIPANT ID:	USUBJID		6-Month FUP		onth FOF
Assessment Date:	//	TUDTC_	nm / dd / yyyy)	STAFF ID:	QSEVAL
FORM COMPLE	TION STATUS	1-CRF Administered 2-Participant refused 3-Staff Member did no			dminister t

(Independent Assessor Completed)

Complete this questionnaire immediately after the NSMF (Non-Study Medical Services – Follow-Up), or the NSMS at the 1-Week Follow-Up visit.

### **TUORRES**

100	IXIXEO		
Yes	No		TUTEST/ TUTESTCD
1	0	1.	Since your last assessment, have you received treatment from a counselor/psychiatrist/psychologist/social worker where the primary focus was on trauma related issues or symptoms?
			(IF NO OR NOT ANSWERED, THEN END QUESTIONNAIRE. OTHERWISE, COMPLETE Q2 AND Q3.)
		2.	(If YES) How many times did you see a counselor/psychiatrist/psychologist/social worker for trauma specific treatment since your last assessment?
		3.	(If YES) How many times did you see a counselor/psychiatrist/psychologist/social worker for trauma specific treatment in the last 30 days?

**STUDYID** 

**DOMAIN: QS** 

STUDY BLIND INTEGRITY (SBI) = QSCAT

PAGE 1 OF 1

NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial				Seq. Num.:
NODE:			VISITI	NUM EPOCH	
CTP-SITE ID:		STUDY Visit: (circle one)		3-Month FUP 6-Month	
PARTICIPANT ID:	USUBJID				
Assessment Date:	/	/ QSDTC(n	nm / dd / yyyy)	STAFF ID:	QSEVAL
FORM COMPLE	TION STATUS	1=CRF Administered 4=Not enough time to Administer 2=Participant refused 5=No Participant Contact 3=Staff Member did not Administer 6=Other		minister t	

(Independent Assessor Completed)

QSORRES		QSTEST/QSTESTCD
_	1.	Were you informed of this Participant's group assignment? (e.g. Was the study blind broken for this Participant?)
		1 = Yes (Answer question 2) 0 = No
_	2.	If yes, to which group was the Participant assigned?  1 = Experimental (Seeking Safety)  2 = Control (Women's Health Education)

**STUDYID** 

### STUDY TERMINATION - FOLLOW-UP (STF)

NIDA-CTN-0015

DOMAIN: DS PAGE 1 OF 1

Seq. Num.:

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NODE:					STUDY Visit:	EPOCH 12-Month FUP			VISITNUM				
	CTP-SITE ID:							FUP					
PARTICIPANT ID: _			USUBJID		, ,	EPOCH VISITNUM							
Assessment Date: / /					_ /	DSDTC (mm / dd / yyyy)		STAFF ID:					
FORM COMPLETION STATUS					2	-CRF Administered -Participant refused -Staff Member did not		4=Not enough time to 5=No Participant Cont 6=Other					
Independent Assessor Completed)  DSCAT=DISPOSITION EVENT													
DSTERM/DSDECOD DM.RFENDTC													
	Date of Follow-Up Phase completion or early termination:DSSTDTC												
	QNAM = DSNUMVIS, QLABEL = NUMBER OF FOLLOW-UP VISITS, IDVAR = DSSEQ  2. Number of Follow-Up Phase visits completed.												
YES	NO	UNK	QNAM	= DSNUMVI	S, C	LABEL = NUM	BER OF FO	LLOW-UP VISIT	S, IDVAR	= DSSEQ			
1	1 0 UNK QNAM = DSNUMVIS, QLABEL = NUMBER OF FOLLOW-UP VISITS, IDVAR = DSSEQ 1 0 -9 3. Did the Participant terminate before the end of the Follow-Up Phase (early termination)? (If No, then end questionnaire. If Yes or UNK, then complete questions 4 through 8.)												
	osoc	CUR		REASON FO	R EA	ARLY TERMINAT	ION						
YES	NO	UNK		Complete this s	ection	n only if answered, "	Yes" or "Unk" In	question 3.					
1	0	-9	4.	Did the Partic	ipant	t refuse to continu	e (discontinue	at her request)?	DSTER	M/DSDECOD			
1	0	-9	5.	Was the Participant lost to follow-up (lost contact)?									
1	0	-9	6.	Was the Participant terminated for clinical reasons?									
1	0	-9	7.	Was the Participant terminated for some other reason? (If yes, describe in question 8.)									
			8.	If any questio	n ab	ove was answere	d Yes, then pr	ovide details:					

Women's Treatment For Trauma And Substance Use Disorders:

A Randomized Clinical Trial

RDOMAIN=DS IDVAR=VISITNUM

Modified: 10/2/2003

Variables COVAL

**COREF=STUDY TERMINATION FOLLOW UP**